

Chapter

3

ProFoRMS




CHAPTER 3 - PROFORMS

The **Protocol and Form Research Management System (ProFoRMS)** module provides the tools for protocol management, data capture, and is a clinical trial/research module. ProFoRMS is a web-based data collection/research application organized by modules, with a user-friendly interface designed to help researchers to manage individual studies, subjects, eCRFs (electronic Case Report Forms), data collection, define electronic case report forms, schedule, and collect clinical data, and then export, analyze, and report on the data. This module is based on NICHD's Clinical Trial Database (CTDB).

WARNING!





ICON KEY

 Notes

 Important

Information

Things to Note:

-  **Before a protocol can be created, please make sure that the following has been completed:**
 -  A study has been created and approved in the Data Repository;
 -  e-Form(s) has been published in the Data Dictionary; and
 -  Proper permissions are granted to the e-Forms (if the eform is not standardized) for users who are collecting data against the form.

3.1 OBJECTIVE

This chapter provides information for users on how to:

- ❖ Manage Protocol
- ❖ Manage Subjects
- ❖ Collect Data
- ❖ Reports and Data Query

3.2 SYSTEM FUNCTIONS

The main function of ProFoRMS is to provide the tools that help to optimize the clinical study process including the basic functions of managing protocols, subjects as well as data access and account management. Early deployment of ProFoRMS in the study start-up activities, such as site identification, initiation of subject visits, and collection of all the necessary regulatory documents, can save researchers' time and improve the overall process.

As a web-based database application, BRICS provides real-time tools that support:

- ❖ Data Contribution
- ❖ Report and Query Data
- ❖ Collect Data

Once a study is running, ProFoRMS can assist users to keep track of subject visits, data collection and of all the relevant forms and regulatory documents. This provides a strong snapshot of progress in terms of study progress and site activation. The ability to track this information ensures that any potential delays can be identified quickly and addressed.

3.3 PROFORMS ROLES AND PRIVILEGES

The table below describes the specific roles with associated privileges to ProFoRMS module.


Role/Access	Privilege
Global Administrator Access	Create, design, and administer forms for prospective collection
Non-Admin Access	Users with this role can view forms and collect data
All Privileges	Create, design, and administer forms for prospective collection
Associate Investigator	Same as PI, except AI cannot add/initiate a study.
Clinical Research Associate	Can view anything but not allowed to change except adding QA Monitor query
Data Entry	Users with this role can view forms and collect data
Data Entry Users	This Role includes: - Viewing: Protocol/Study, Visit Types, Data entry, Forms, and Attachments – Editing/managing scheduled visits – Data entry/editing/viewing e-forms – Viewing response data.
Principal Investigator	Create, design, and administer forms for prospective collection

3.4 USING ProFORMS



The **ProFoRMS** module (including sub-modules) are available within the BRICS Workspace.

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 Notes

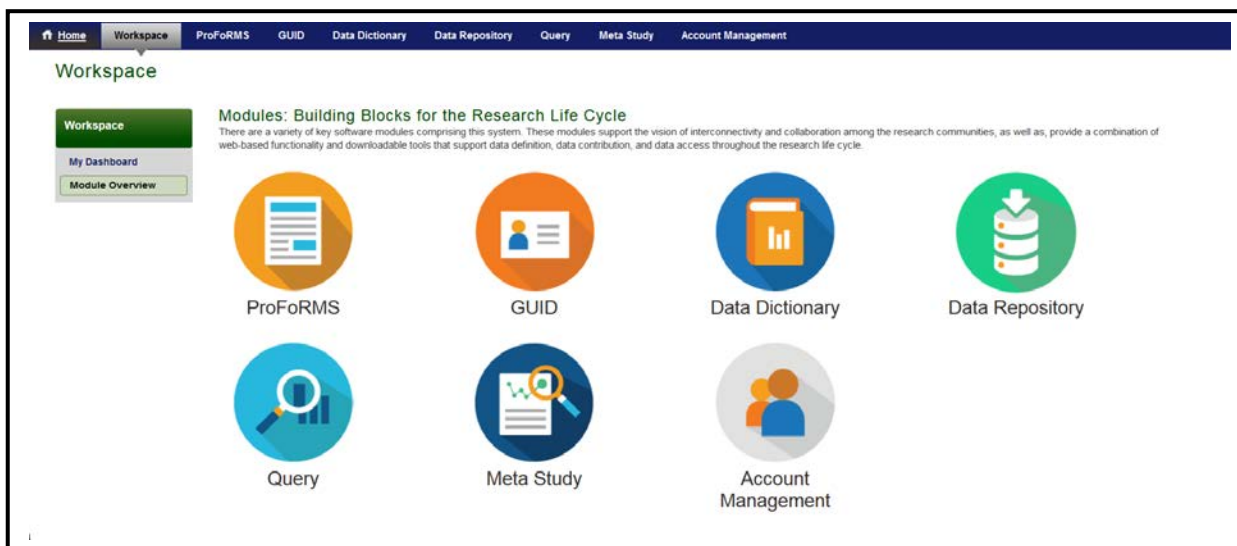
 Important
Information

Things to Note:

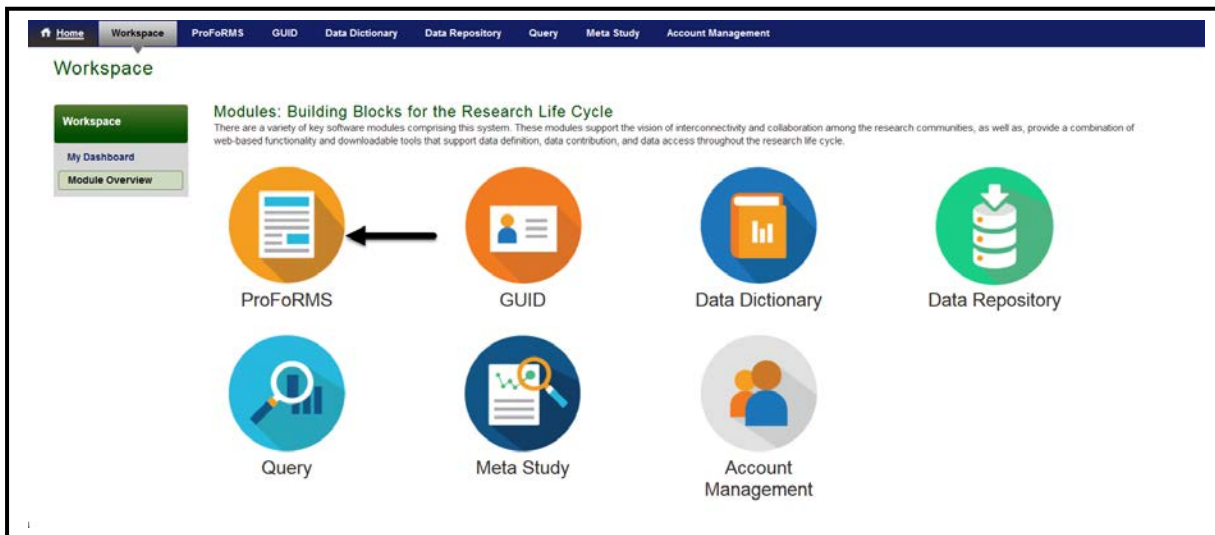
-  The best user experience with navigating through the ProFoRMS module is with the latest Firefox browser
-  Java Runtime Environment (JRE) version 8 or higher is required. [Check](#) your version of Java.

To access the [ProFoRMS](#) module: Perform the following actions:

1. Login and navigate to the **Workspace** screen where all modules you have access to are displayed.




2. Click the **ProFoRMS** module to enter ProFoRMS.



WARNING!


ICON KEY

 Notes

 Important

Information

Things to Note:

-  A Protocol must be created first before users can navigate to My Subjects and start adding subjects or managing and/or editing subjects. Refer to [section 3.5.2](#) of this document instruction on creating a protocol.

3.5 MY SUBJECTS

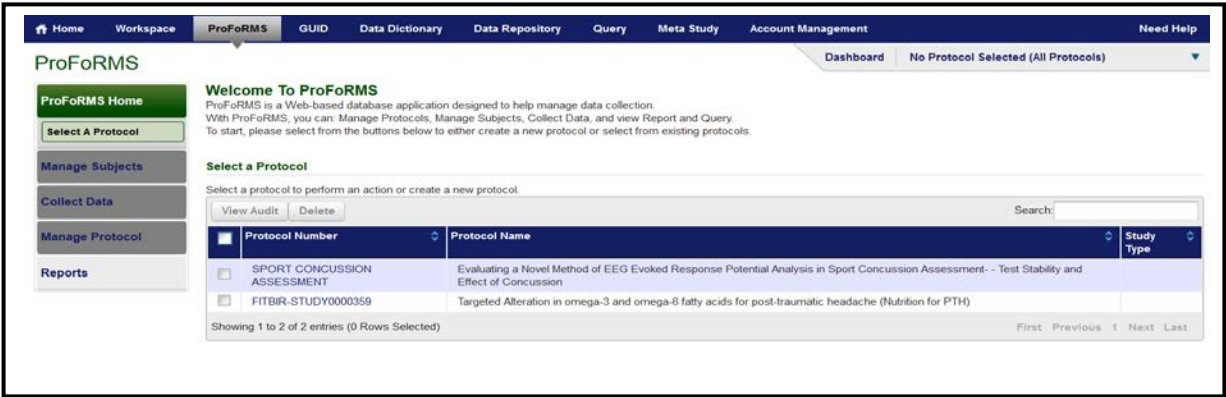
This feature is designed to help the researchers to add and edit subject information, schedule subject visits, track individual subjects across multiple studies within the system, upload subject related document, etc.

The **My Subjects** page lists all subjects currently enrolled into the protocol. The user can sort the list of subjects by **Subject ID**, **First** and **Last Name**, **Status**, **Group**, **Validation Status**, **Study Number**, and the **Monitor Query** status. The table also has a simple search box.

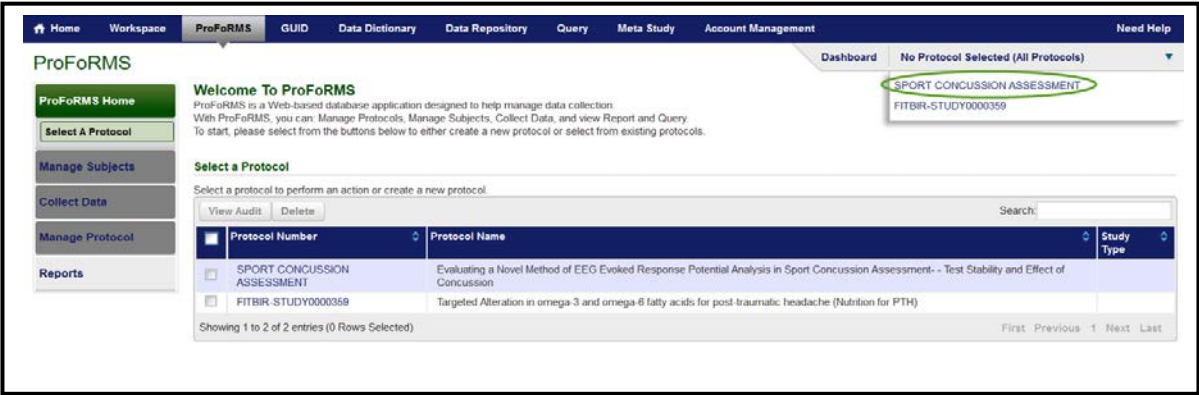
- The menu options allows the user:
- ❖ To view and edit subject's information;
 - ❖ To view and upload subject related documents;
 - ❖ To view forms completed for a selected subject;
 - ❖ To view the audit information;
 - ❖ To add the monitor query;
 - ❖ To schedule a visit;
 - ❖ To delete selected subjects; and
 - ❖ To search for a subject using a keyword.

3.5.1 Access My Subject

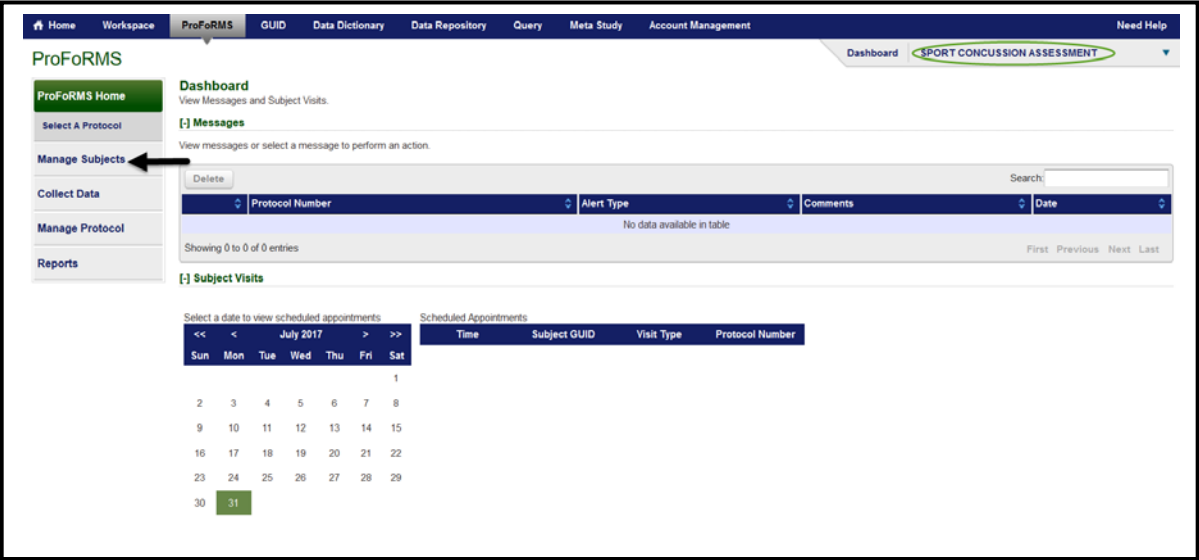
- To access **My Subjects** page: Perform the following actions:
1. Login to the system.
 2. Navigate to the **ProFoRMS** module




3. Select a **Protocol** by using the drop-down menu located on the top right-hand corner.
Note: Many of the features on the left-hand side will not be active until a protocol is selected. If you are unable to select a protocol from the drop-down menu, please contact the [Operations Team](#) for assistance.



4. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



- My Subjects** page appears with a list that can be sorted by clicking on the arrows on any field using the  symbol. While in the Subject view, you may *View Subject lists*, *Search for Subject* or *Select Subjects* to perform any desired action.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

SPORT CONCUSSION ASSESSMENT

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

My Subjects

View subject list, search for a subject, or select subjects to perform an action.

[+] Advanced Search

My Subjects

Select a subject to perform an action.

Edit

View

Attachments

All Completed eForms

View Audit

Schedule Visit

Delete

Sorting feature

Search:

	GUID	Subject ID	Status	Validated	Protocol
<input type="checkbox"/>	TBPE259ZBB	511	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIAK551TN6	512	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBINE795JUR	513	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBYC163KT9	514	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIVE769VU0	515	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBICG715VZJ	516	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBRZ271WLV	517	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIFV294KDW	518	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIAH991HFU	520	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBLV748PY5	521	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBBH925ANZ	522	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIGP371ZKD	523	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIGB632BGK	524	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBLV223MGZ	525	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIAL563DHH	526	Active		SPORT CONCUSSION ASSESSMENT

Showing 1 to 15 of 29 entries (0 Rows Selected) Export options: CSV | Excel

First

Previous

1

2

Next


Last

ICON KEY

Notes

Important Information

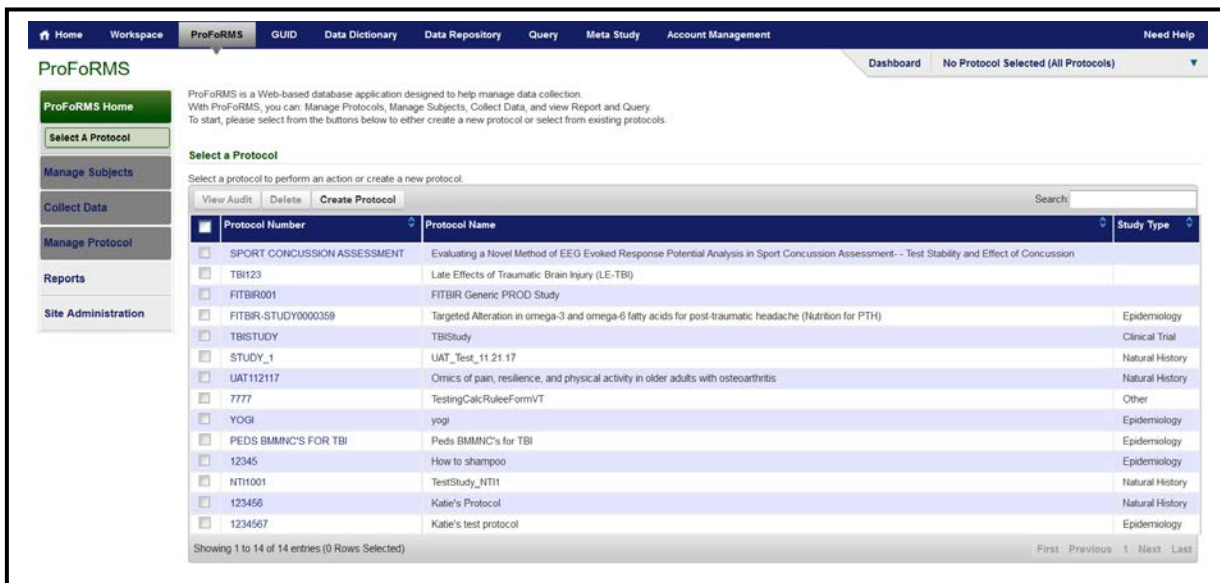
Things to Note:

 The **My Subjects** toolbar is available when the user selects a subject from the list.

3.5.2 Create a Protocol (Select a Protocol if already created)

To create a **Protocol**: Perform the following actions:

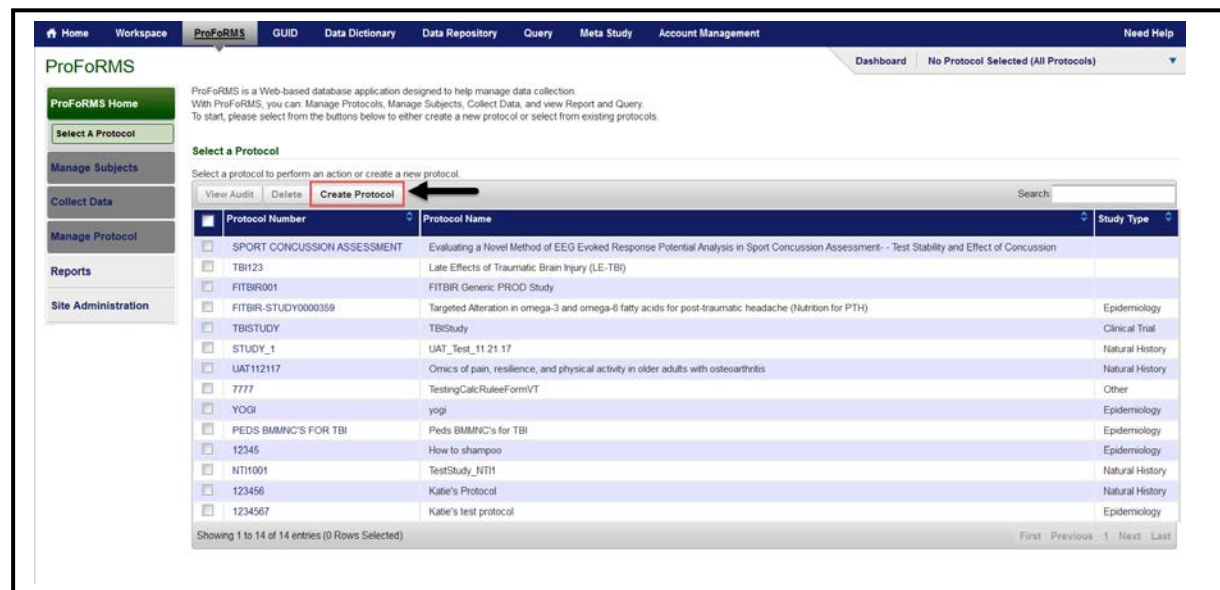
1. Navigate to the **ProFoRMS** home page.



The screenshot shows the ProFoRMS home page. The 'Create Protocol' button is highlighted in the 'Select a Protocol' section. The table below lists the protocols available in the system.

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
TBI123	Late Effects of Traumatic Brain Injury (LE-TBI)	
FITBIR001	FITBIR Generic PROD Study	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Epidemiology
TBISTUDY	TBISTudy	Clinical Trial
STUDY_1	UAT_Test_11.21.17	Natural History
UAT112117	Omics of pain, resilience, and physical activity in older adults with osteoarthritis	Natural History
7777	TestingCalcRuleFormVT	Other
YOGI	yogi	Epidemiology
PEDS BMMNC'S FOR TBI	Peds BMMNC's for TBI	Epidemiology
12345	How to shampoo	Epidemiology
NTI1001	TestStudy_NTII	Natural History
123456	Katie's Protocol	Natural History
1234567	Katie's test protocol	Epidemiology

2. Click the **Create Protocol** button.

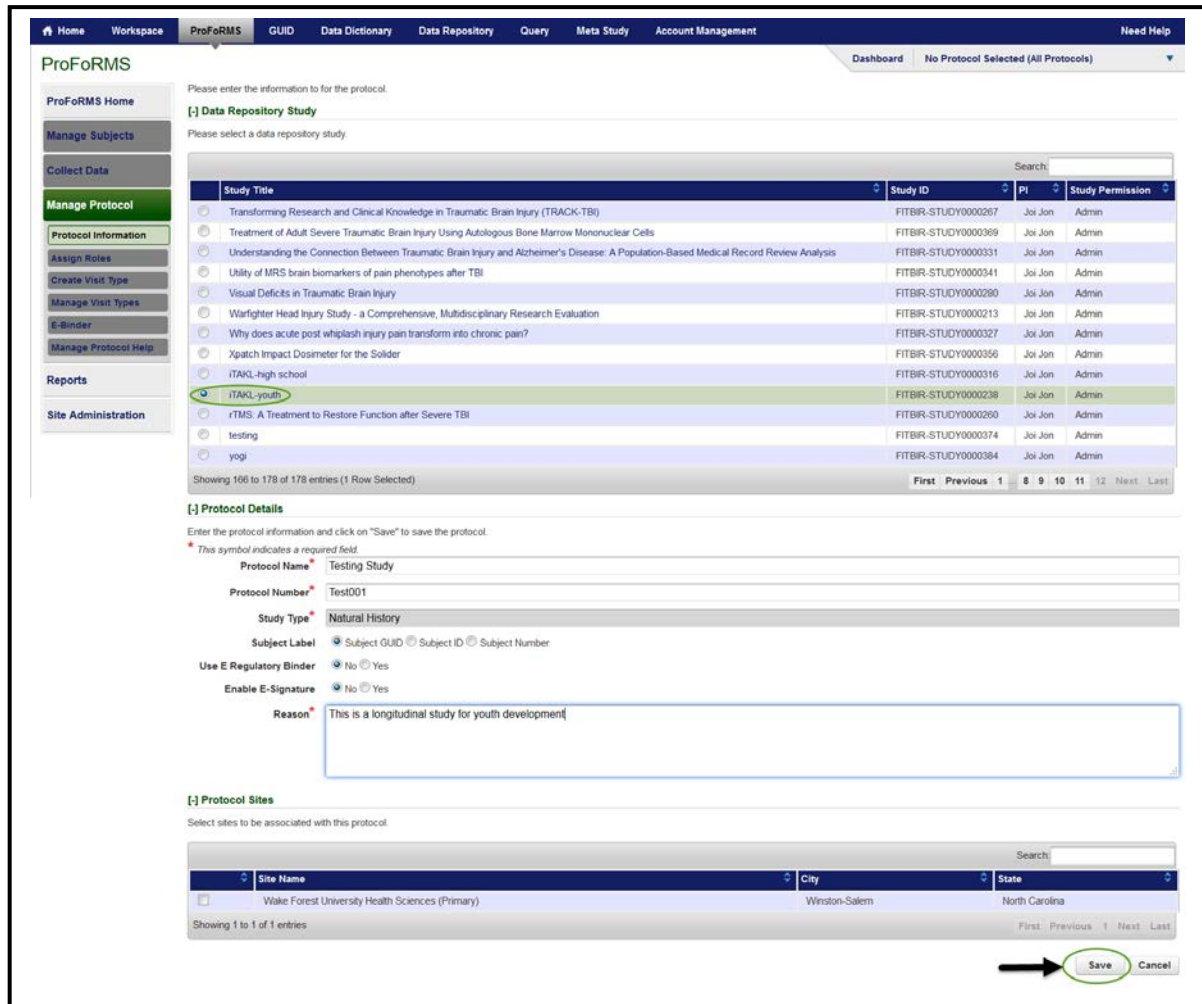


The screenshot shows the ProFoRMS home page with the 'Create Protocol' button highlighted and an arrow pointing to it. The table below lists the protocols available in the system.

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
TBI123	Late Effects of Traumatic Brain Injury (LE-TBI)	
FITBIR001	FITBIR Generic PROD Study	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Epidemiology
TBISTUDY	TBISTudy	Clinical Trial
STUDY_1	UAT_Test_11.21.17	Natural History
UAT112117	Omics of pain, resilience, and physical activity in older adults with osteoarthritis	Natural History
7777	TestingCalcRuleFormVT	Other
YOGI	yogi	Epidemiology
PEDS BMMNC'S FOR TBI	Peds BMMNC's for TBI	Epidemiology
12345	How to shampoo	Epidemiology
NTI1001	TestStudy_NTII	Natural History
123456	Katie's Protocol	Natural History
1234567	Katie's test protocol	Epidemiology

4. *Type, Reason etc..*) (all required fields (the ones marked with a red asterisk (*)). Remember to select the **Protocol Site(s)** to be associated with your protocol

Before saving a protocol, you must also select a study in the Data Repository (doing this will automatically populate the Study Type required field information). Click the **Save** button. The new protocol will appear in the protocol list under My Protocols.



The screenshot shows the ProFoRMS web application interface. The top navigation bar includes links for Home, Workspace, ProFoRMS, GUID, Data Dictionary, Data Repository, Query, Meta Study, Account Management, and Need Help. The ProFoRMS section is active, showing a sidebar with options like Manage Subjects, Collect Data, Manage Protocol, and Reports. The main content area is titled "Data Repository Study" and displays a table of available studies. The "iTAKL-youth" study is selected. Below the table, the "Protocol Details" section is visible, containing fields for Protocol Name, Protocol Number, Study Type, Subject Label, Use E Regulatory Binder, Enable E-Signature, and Reason. The "Protocol Sites" section at the bottom shows a table of available sites, with "Wake Forest University Health Sciences (Primary)" selected. A green circle highlights the "Save" button at the bottom right of the form.

ProFoRMS

Please enter the information for the protocol.

[+] Data Repository Study

Please select a data repository study.

Study Title	Study ID	PI	Study Permission
Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI)	FITBIR-STUDY0000267	Joi Jon	Admin
Treatment of Adult Severe Traumatic Brain Injury Using Autologous Bone Marrow Mononuclear Cells	FITBIR-STUDY0000369	Joi Jon	Admin
Understanding the Connection Between Traumatic Brain Injury and Alzheimer's Disease: A Population-Based Medical Record Review Analysis	FITBIR-STUDY0000331	Joi Jon	Admin
Utility of MRS brain biomarkers of pain phenotypes after TBI	FITBIR-STUDY0000341	Joi Jon	Admin
Visual Deficits in Traumatic Brain Injury	FITBIR-STUDY0000290	Joi Jon	Admin
Warfighter Head Injury Study - a Comprehensive, Multidisciplinary Research Evaluation	FITBIR-STUDY0000213	Joi Jon	Admin
Why does acute post whiplash injury pain transform into chronic pain?	FITBIR-STUDY0000327	Joi Jon	Admin
Xgatch Impact Dosimeter for the Soldier	FITBIR-STUDY0000356	Joi Jon	Admin
iTAKL-high school	FITBIR-STUDY0000316	Joi Jon	Admin
iTAKL-youth	FITBIR-STUDY0000238	Joi Jon	Admin
iTMS: A Treatment to Restore Function after Severe TBI	FITBIR-STUDY0000290	Joi Jon	Admin
testing	FITBIR-STUDY0000374	Joi Jon	Admin
yogi	FITBIR-STUDY0000384	Joi Jon	Admin

Showing 106 to 178 of 178 entries (1 Row Selected)

[+] Protocol Details

Enter the protocol information and click on "Save" to save the protocol.

* This symbol indicates a required field.

Protocol Name* Testing Study

Protocol Number* Test001

Study Type* Natural History

Subject Label ☒ Subject GUID ☐ Subject ID ☐ Subject Number

Use E Regulatory Binder ☒ No ☐ Yes

Enable E-Signature ☒ No ☐ Yes

Reason* This is a longitudinal study for youth development

[+] Protocol Sites

Select sites to be associated with this protocol.

Site Name	City	State
<input checked="" type="checkbox"/> Wake Forest University Health Sciences (Primary)	Winston-Salem	North Carolina

Showing 1 to 1 of 1 entries

Save **Cancel**

3.5.3 Selecting a Protocol

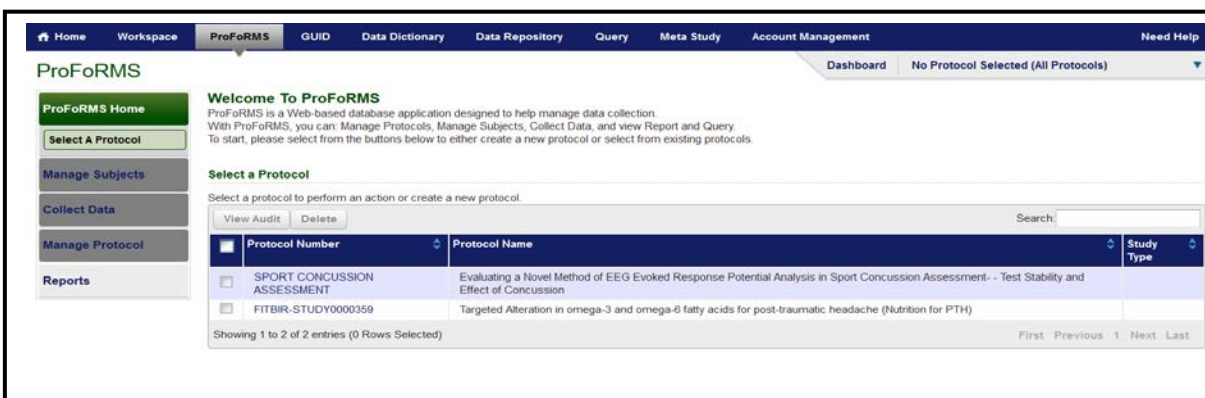
The viewing and selecting a protocol can be done in ProFoRMS via two ways:

- ❖ Using the pick a protocol drop-down list; and
- ❖ Using the Select a Protocol left-hand menu

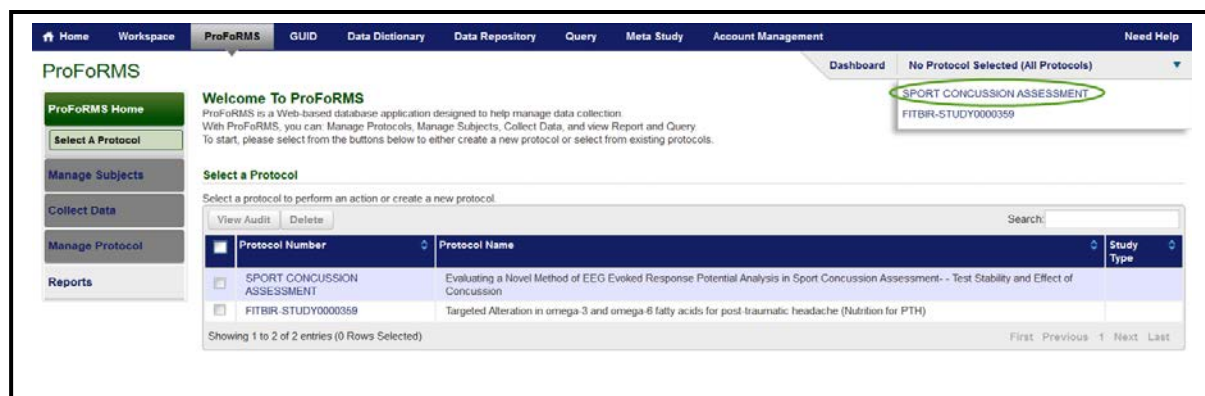
Using the Drop-down List

To select a **Protocol in ProFoRMS** using the drop-down list: Perform the following actions:

1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand. The list of available protocols appears.



- Click on the desired Protocol. The system will load the selected protocol data including the list of subject visits and messages.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TBISTUDY

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Site Administration

Dashboard

View Messages and Subject Visits

Messages

View messages or select a message to perform an action.

Delete

Search

Protocol Number	Alert Type	Comments	Date
No data available in table			

Showing 0 to 0 of 0 entries

First Previous Next Last

Subject Visits

Select a date to view scheduled appointments

<<

<

August 2017

>

>>

Time	Subject GUID	Visit Type	Protocol Number
Sun	Mon	Tue	Wed
1	2	3	4
5	6	7	8
9	10	11	12
13	14	15	16
17	18	19	20
21	22	23	24
25	26	27	28
29	30	31	

Using the Select a Protocol button:

To select a Protocol in ProFoRMS using the protocol button: Perform the following actions:

- Navigate to the ProFoRMS module

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

No Protocol Selected (All Protocols)

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol.

View Audit

Delete

Search

Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
<input type="checkbox"/> FTBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected)

First Previous 1 Next Last

2. Select a **Protocol** by clicking on the **Select A Protocol** button on the left-hand. The list of protocols appears. Select a protocol by clicking on the desired protocol number.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

No Protocol Selected (All Protocols)

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Site Administration

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol

View Audit

Delete

Create Protocol

Search:

Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
<input type="checkbox"/> TB123	Late Effects of Traumatic Brain Injury (L-E-TBI)	
<input type="checkbox"/> FITBR001	FITBR Generic PROD Study	
<input type="checkbox"/> FITBR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Epidemiology
<input checked="" type="checkbox"/> TBISTUDY	TBISTudy	Clinical Trial
<input type="checkbox"/> STUDY_1	UAT_Test_11.21.17	Natural History
<input type="checkbox"/> UAT112117	Omics of pain, resilience, and physical activity in older adults with osteoarthritis	Natural History
<input type="checkbox"/> 7777	TestingCalcRuleFormVT	Other
<input type="checkbox"/> YOGI	yogi	Epidemiology
<input type="checkbox"/> PEDS BMNC'S FOR TBI	Peds BMNC's for TBI	Epidemiology
<input type="checkbox"/> 12345	How to shampoo	Epidemiology
<input type="checkbox"/> NT11001	TestStudy_NT11	Natural History
<input type="checkbox"/> 123456	Katie's Protocol	Natural History
<input type="checkbox"/> 1234567	Katie's test protocol	Epidemiology
<input type="checkbox"/> TEST001	Testing Study	Natural History

Showing 1 to 15 of 15 entries (1 Row Selected)

First Previous 1 Next Last

3. The system will load the selected protocol data including the list of subject visits and messages.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TBISTUDY

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Site Administration

Dashboard

View Messages and Subject Visits.

[-] Messages

View messages or select a message to perform an action.

Delete

Search:

Protocol Number	Alert Type	Comments	Date
No data available in table			

Showing 0 to 0 of 0 entries

First Previous Next Last

[-] Subject Visits

Select a date to view scheduled appointments

Scheduled Appointments

<<

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August 2017

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Sun	Mon	Tue	Wed	Thu	Fri	Sat
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

Time	Subject GUID	Visit Type	Protocol Number
------	--------------	------------	-----------------

3.6 MANAGE SUBJECTS

This feature is designed to help you **Edit, View, View All Completed eForms, Schedule Subject Visits and Delete Subjects** and track individual subjects across multiple studies within the system, and upload subject-related documents.

Edit View Attachments All Completed eForms View Audit Schedule Visit Delete

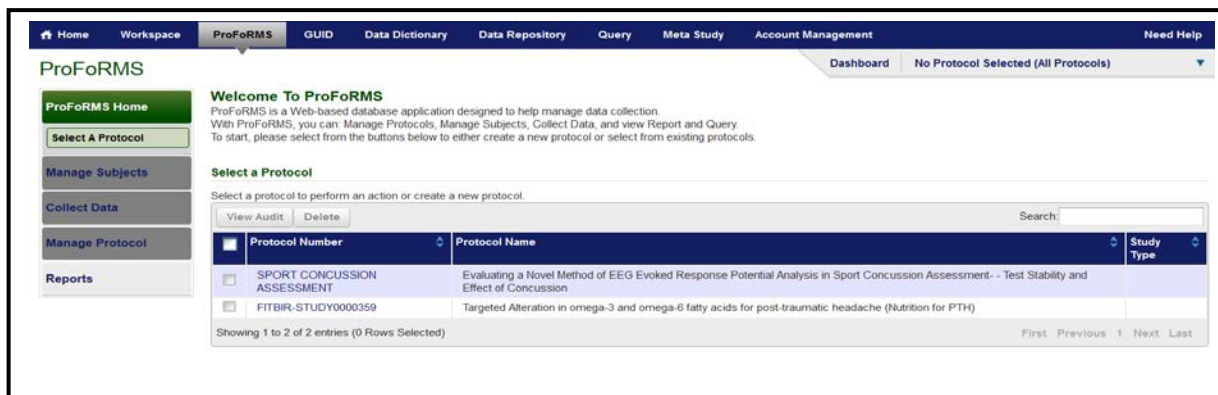
Search:

3.6.1 Add Subject

To add a subject (a research participant) to a Protocol, the subject must be provided with a unique Identification number (ID). The goal is to provide the identification number, which allows the researchers to associate data with the subject without exposing or transferring the subject's Personally Identifiable Information (PII). This is done by using the Global Unique Identifier (GUID). For more information about the GUID, please refer to [Chapter 6 GUID](#).

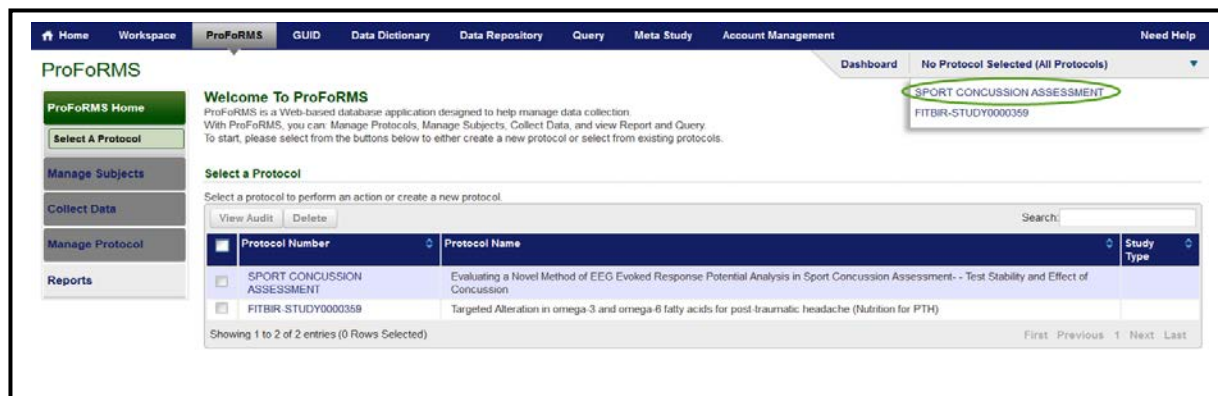
To Add Subject: Perform the following actions:

1. Navigate to the **ProFoRMS** module

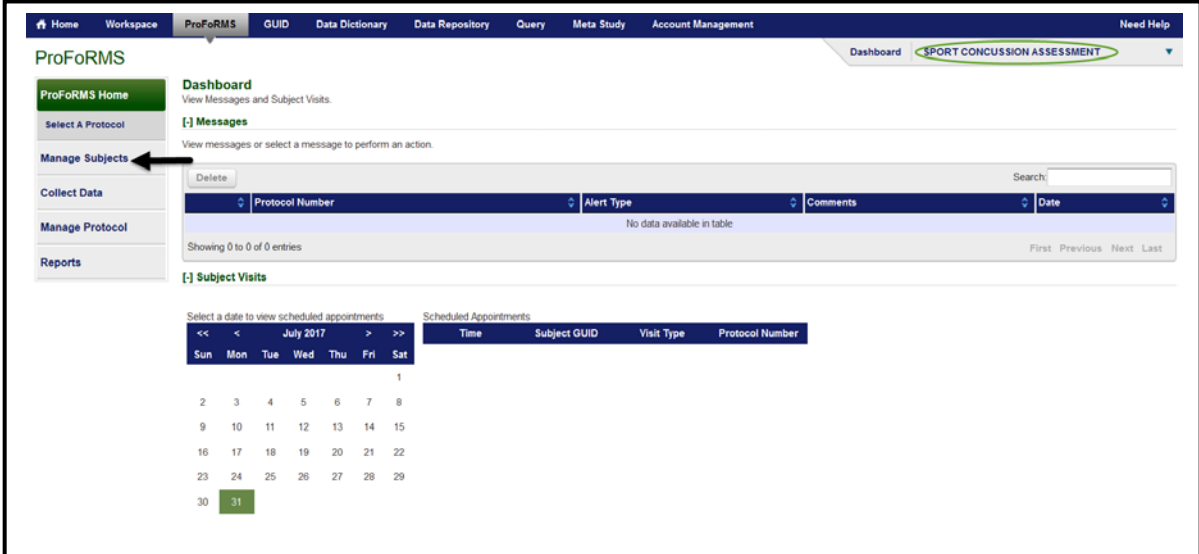



Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
<input type="checkbox"/> FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

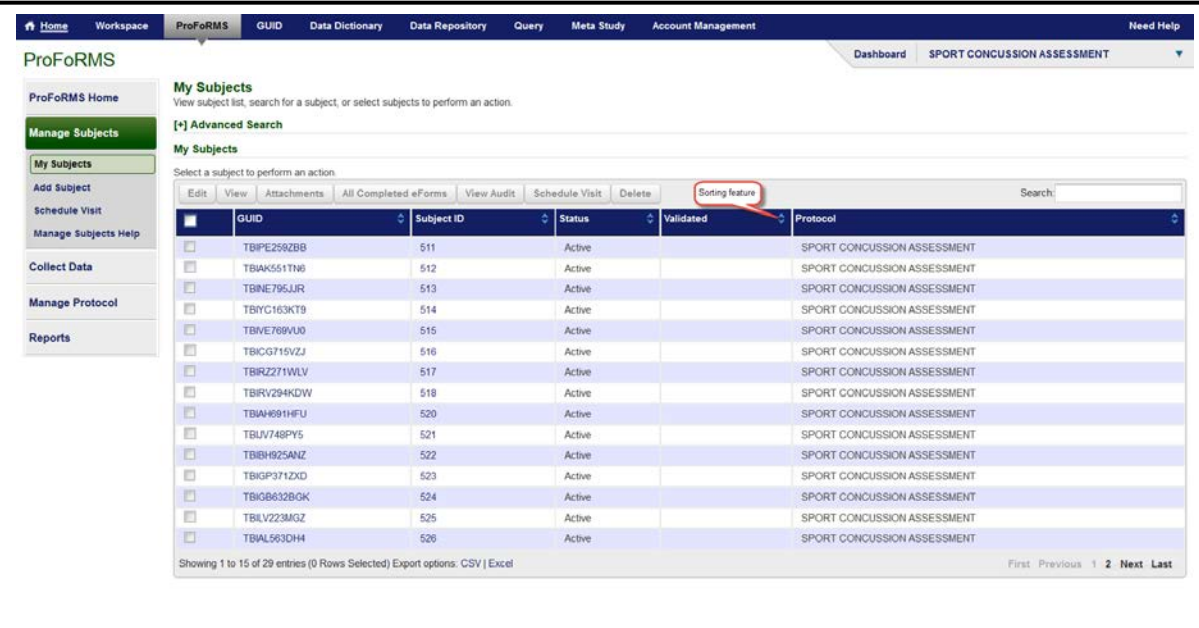
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



4. My Subjects page appears with in a list that can be sorted by clicking on the arrows on any field using the  symbol.



5. Click the **Add Subject** tab on the left-side tool bar.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

ProFoRMS

Dashboard

TBI STUDY

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

Add Subject

Please enter subject information, add protocol information and other fields to add a subject.

[-] Subject Information

If the subject does not have a GUID or Pseudo-GUID created in the system, click on the "Create GUID" button below to launch the GUID Tool. The GUID Tool will allow you to enter the information necessary to generate a GUID or Pseudo-GUID for a subject. **Once the GUID is generated, a pop-up will appear. The "Copy" button will copy the GUID to your clipboard so the generated ID can be pasted into the "GUID or Pseudo-GUID" text field in the Subject Information section. The "OK" button will exit the pop-up without saving the GUID to your clipboard; however, the generated ID can still be copied to your clipboard by clicking on the "Copy GUID" button on the GUID Tool.**

Launch GUID Tool

* This symbol indicates a required field

GUID or Pseudo-GUID*

Validate GUID

Additional Information Associated with Subject

Protocol Subject ID *

Recruited ☐

Biorepository Subject ID


[*] Protocol

[*] Attachments

Save

Reset

Cancel

- Enter the required **Subject Information** to add a subject. (**Note:** Study Subject ID is unique across the system. Sites entering this information must use a prefix (i.e. UTSW_001, JHU_001))using the  feature). Expand the form to Enter the **Study Information** and attach any relevant documents as required. Making sure the attachment doesn't contain any PII. Type in the GUID and click the **Validate GUID** button to validate the GUID for the current subject. After entering all the required protocol information, click the **Save** button.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TBI STUDY

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

Please enter subject information, add protocol information and other fields to add a subject.

[-] Subject Information

If the subject does not have a GUID or Pseudo-GUID created in the system, click on the "Create GUID" button below to launch the GUID Tool. The GUID Tool will allow you to enter the information necessary to generate a GUID or Pseudo-GUID for a subject. Once the GUID is generated, a pop-up will appear. The "Copy" button will copy the GUID to your clipboard so the generated ID can be pasted into the "GUID or Pseudo-GUID" text field in the Subject Information section. The "OK" button will exit the pop-up without saving the GUID to your clipboard; however, the generated ID can still be copied to your clipboard by clicking on the "Copy GUID" button on the GUID Tool.

Launch GUID Tool

* This symbol indicates a required field

GUID or Pseudo-GUID* TBIDEMOWR473JK4

Validate GUID

Additional Information Associated with Subject

Protocol Subject ID

Biorepository Subject ID

Recruited

[-] Protocol

Please enter protocol information

[-] Attachments

Please make sure the attachment doesn't contain any PII.

Name*

Attachment*

Description

Category

None

Add

Cancel

Edit

View Audit

Delete

Search

Name

Description

Category

There are no attachments to display at this time.

none

none

none

Showing 1 to 1 of 1 entries

First

Previous

1

Next

Last

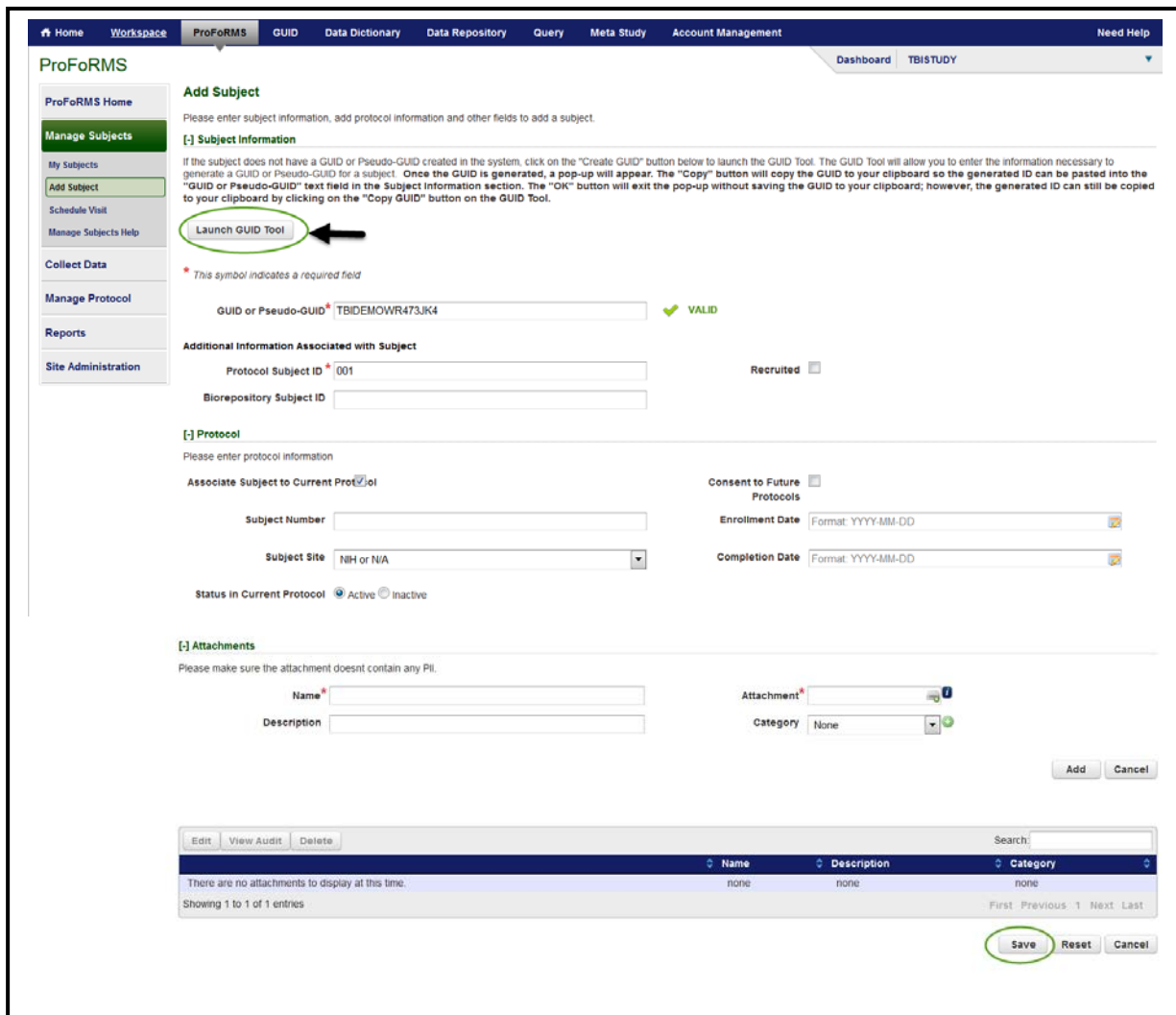
Save

Reset

Cancel

- If the subject does not have a **GUID** or **Pseudo-GUID** created in the system, Click on the **"Create GUID"** button below to launch the GUID Tool. ([See section 3.7.2 for instruction on launching the GUID tool](#)). Mandatory fields are marked with asterisk *. Once all the mandatory fields are complete, click the **Save** button.

Click the **Save** button to return to **My Subject** screen where the newly added Subject can be viewed.



ProFoRMS

Add Subject

Please enter subject information, add protocol information and other fields to add a subject.

[+] Subject Information

If the subject does not have a GUID or Pseudo-GUID created in the system, click on the "Create GUID" button below to launch the GUID Tool. The GUID Tool will allow you to enter the information necessary to generate a GUID or Pseudo-GUID for a subject. **Once the GUID is generated, a pop-up will appear. The "Copy" button will copy the GUID to your clipboard so the generated ID can be pasted into the "GUID or Pseudo-GUID" text field in the Subject Information section. The "OK" button will exit the pop-up without saving the GUID to your clipboard; however, the generated ID can still be copied to your clipboard by clicking on the "Copy GUID" button on the GUID Tool.**

Launch GUID Tool

* This symbol indicates a required field

GUID or Pseudo-GUID* TBIDEMOWR473JK4 VALID

Additional Information Associated with Subject

Protocol Subject ID* 001 Recruited ☐

Biorepository Subject ID

[+] Protocol

Please enter protocol information

Associate Subject to Current Protocol ☐

Subject Number

Subject Site NIH or N/A

Status in Current Protocol ☒ Active ☐ Inactive

Consent to Future Protocols ☐

Enrollment Date Format: YYYY-MM-DD

Completion Date Format: YYYY-MM-DD

[+] Attachments

Please make sure the attachment doesn't contain any PII.

Name* Attachment*

Description Category None

Add Cancel

Edit View Audit Delete Search:

Name	Description	Category
none	none	none

There are no attachments to display at this time.

Showing 1 to 1 of 1 entries

First Previous 1 Next Last

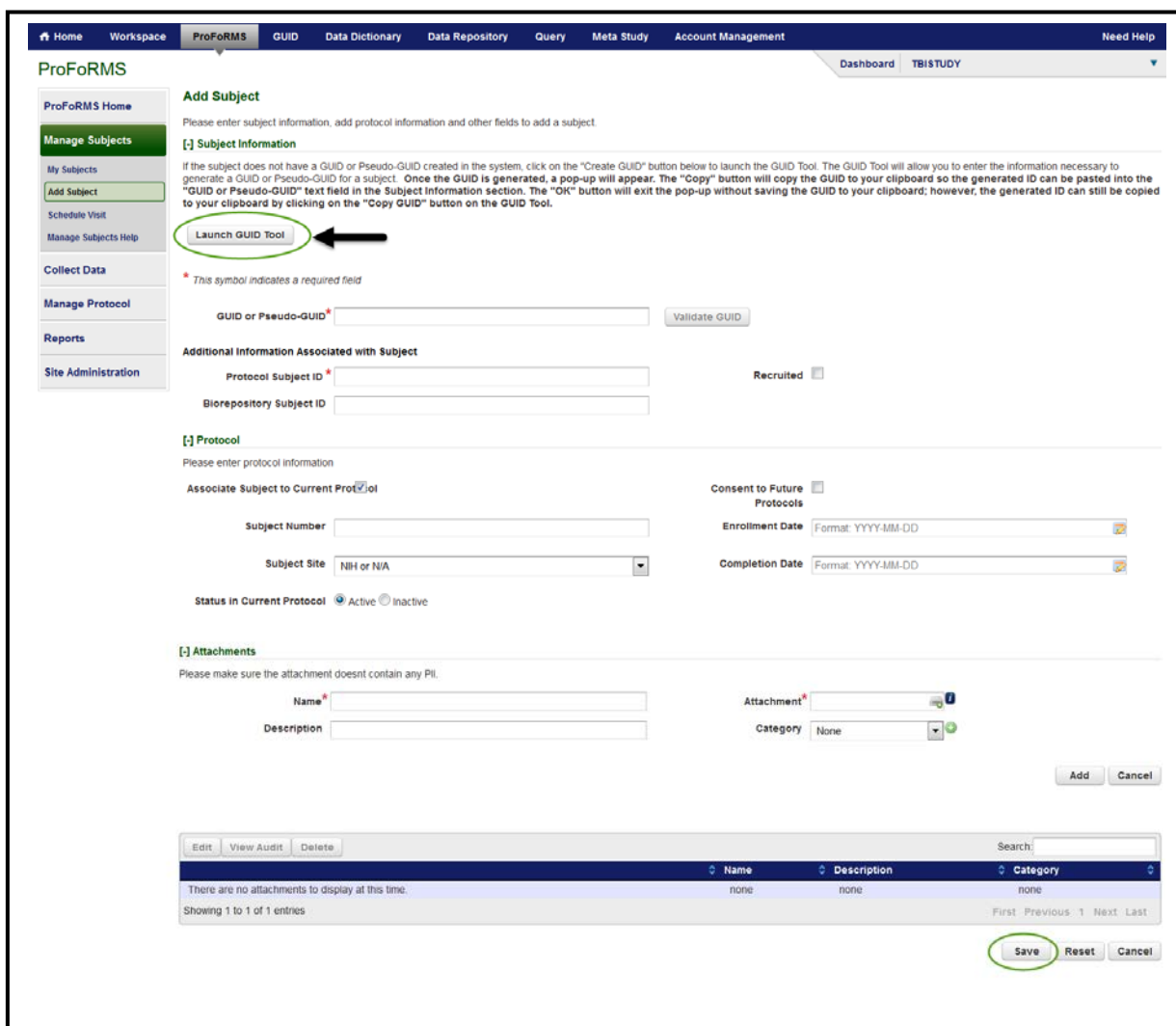
Save Reset Cancel

3.6.2 Launching the GUID Tool

From the **Add Subject** page, you can launch the GUID Tool. **NOTE:** Only Users with correct permissions/access to the GUID module are able to launch the GUID Tool.

To Launch the GUID Tool: Perform the following actions:

1. Click on the **"Launch GUID Tool"** button below to launch the GUID Tool. The GUID Tool will allow you to enter the information necessary to generate a GUID or Pseudo-GUID for a subject. Once the GUID is generated, a pop-up will appear. The **"Copy"** button will copy the GUID to your clipboard so the generated ID can be pasted into the "GUID or Pseudo-GUID" text field in the Subject Information section. The **"OK"** button will exit the pop-up without saving the GUID to your clipboard; however, the generated ID can still be copied to your clipboard by clicking on the **"Copy GUID"** button on the GUID Tool.



ProFoRMS

Add Subject

Please enter subject information, add protocol information and other fields to add a subject.

[+] **Subject Information**

If the subject does not have a GUID or Pseudo-GUID created in the system, click on the "Create GUID" button below to launch the GUID Tool. The GUID Tool will allow you to enter the information necessary to generate a GUID or Pseudo-GUID for a subject. Once the GUID is generated, a pop-up will appear. The "Copy" button will copy the GUID to your clipboard so the generated ID can be pasted into the "GUID or Pseudo-GUID" text field in the Subject Information section. The "OK" button will exit the pop-up without saving the GUID to your clipboard; however, the generated ID can still be copied to your clipboard by clicking on the "Copy GUID" button on the GUID Tool.

Launch GUID Tool

* This symbol indicates a required field

GUID or Pseudo-GUID*

Additional Information Associated with Subject

Protocol Subject ID* Recruited ☐

Biorepository Subject ID

[+] **Protocol**

Please enter protocol information

Associate Subject to Current Protocol ☒

Subject Number

Subject Site

Status in Current Protocol ☒ Active ☐ Inactive

Consent to Future Protocols ☐

Enrollment Date

Completion Date

[+] **Attachments**

Please make sure the attachment doesn't contain any PII.

Name*

Description

Attachment*

Category

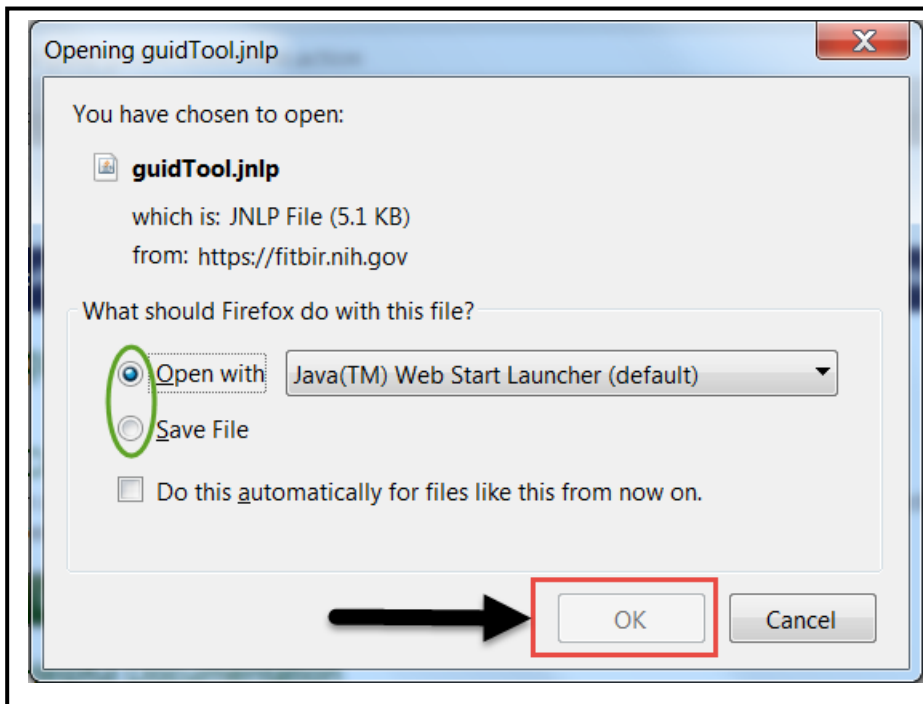
Search:

Name	Description	Category
none	none	none

There are no attachments to display at this time.

Showing 1 to 1 of 1 entries

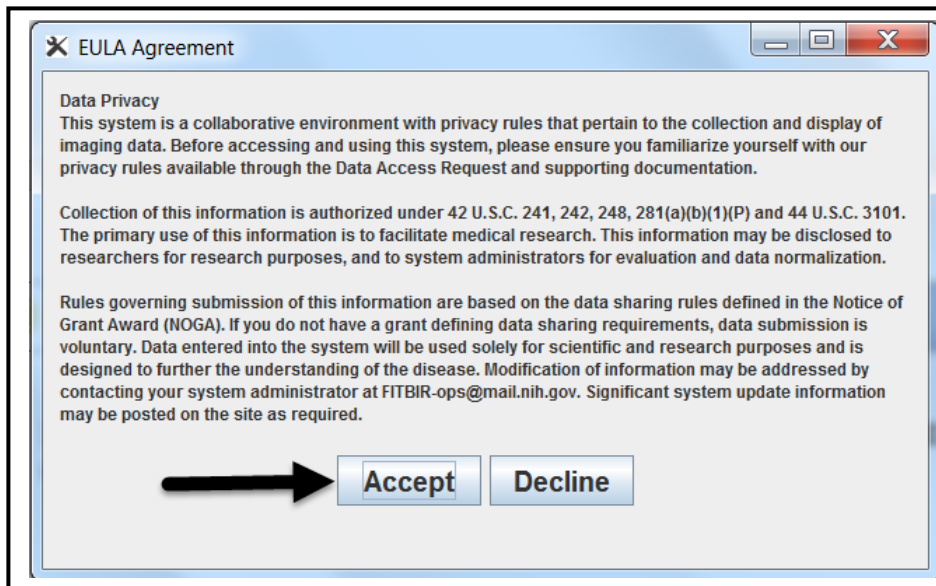
2. In the Opening **guidTool.jnlp** window that appears, Click **Open with Java(TM) Web Start Launcher** (default) and Click **OK**.



3. In the **Java Runtime Environment (JRE)** window that appears next saying "Do you want to run this application?", Click **Run**.



4. The EULA Agreement window appears displaying the data privacy user agreement. Read the agreement and Click **Accept** if you agree. The GUID Client window appears.



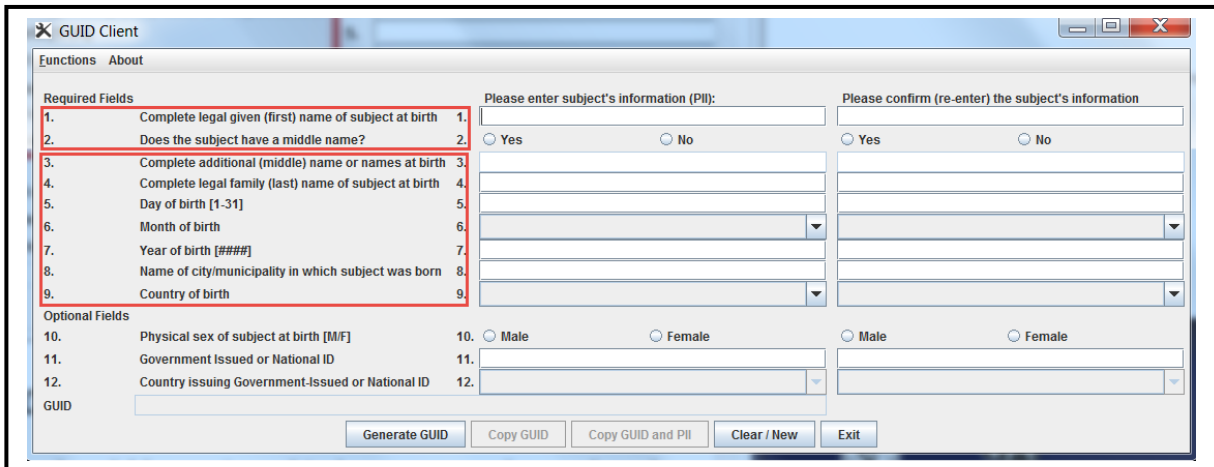
5. The **GUID Client Dialog Box** opens. **Enter the participant's information (Subject's Personal Identifiable Information (PII))** into the dialog box. Re-enter the **Subject's Personal Identifiable Information (PII)** to confirm the subject's information.

The required field names necessary to obtain a valid GUID are listed below:

- ❖ Complete legal given (first) name of subject at birth
- ❖ Select YES if the subject DOES HAVE a Middle Name, NO otherwise
- ❖ Complete additional (middle) name or names at birth
- ❖ Complete legal family (last) name of subject at birth
- ❖ Day of birth [1—31]
- ❖ Month of birth [January-December]
- ❖ Year of birth [####]
- ❖ Name of city/municipality in which subject was born
- ❖ Country of birth

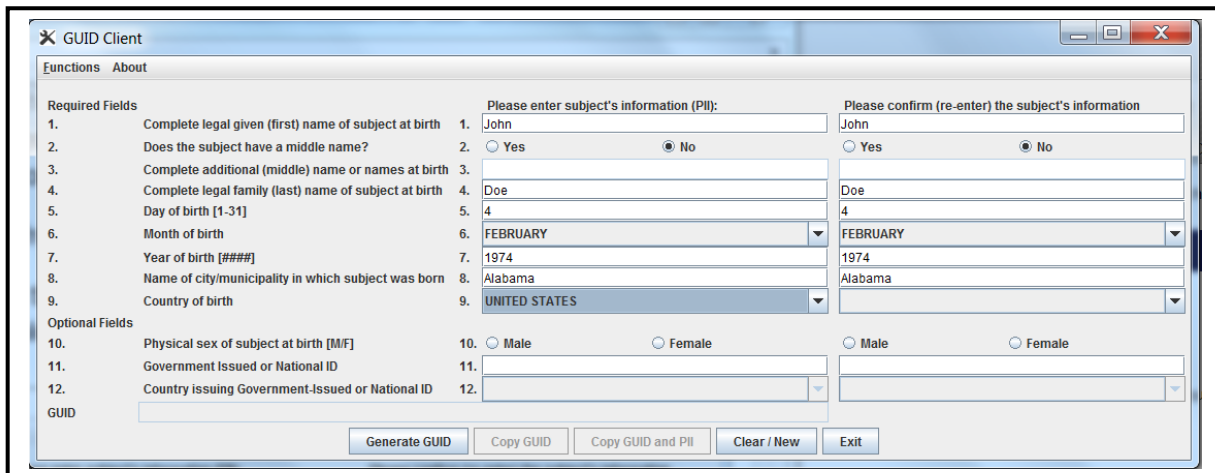
The following are additional fields that can be used, but are not required:

- ❖ Physical sex of subject at birth [Male/Female]
- ❖ Government Issued or National ID number
- ❖ Name of the country issuing the Government or National ID



Required Fields		Please enter subject's information (PII):		Please confirm (re-enter) the subject's information	
1.	Complete legal given (first) name of subject at birth	1.	<input type="text"/>		<input type="text"/>
2.	Does the subject have a middle name?	2.	<input type="radio"/> Yes <input type="radio"/> No		<input type="radio"/> Yes <input type="radio"/> No
3.	Complete additional (middle) name or names at birth	3.	<input type="text"/>		<input type="text"/>
4.	Complete legal family (last) name of subject at birth	4.	<input type="text"/>		<input type="text"/>
5.	Day of birth [1-31]	5.	<input type="text"/>		<input type="text"/>
6.	Month of birth	6.	<input type="text"/>		<input type="text"/>
7.	Year of birth [####]	7.	<input type="text"/>		<input type="text"/>
8.	Name of city/municipality in which subject was born	8.	<input type="text"/>		<input type="text"/>
9.	Country of birth	9.	<input type="text"/>		<input type="text"/>
Optional Fields		10. <input type="radio"/> Male <input type="radio"/> Female		10. <input type="radio"/> Male <input type="radio"/> Female	
11.	Government Issued or National ID	11.	<input type="text"/>		<input type="text"/>
12.	Country issuing Government-Issued or National ID	12.	<input type="text"/>		<input type="text"/>
GUID		<input type="text"/>			

6. To complete the GUID dialog box and obtain the GUID, complete the following steps, starting in the left column of the dialog box:
 - a) Enter in the complete legal given (first) name of subject at birth.
 - b) Select Yes or No depending on whether or not the subject has a middle name. If yes, enter information in field 3.
 - c) Complete the required fields 4-9;
 - d) If information is available, complete the optional fields 10-12. Enter the subject's physical sex at birth into #10 field, the government issued or national ID number into #11 field (note that the list box in #12 field becomes available once data is entered into #11);
 - e) Select the country of issued ID from the list provided.
 - f) Enter the same information into the right column of the dialog box as shown below:



GUID Client

Functions About

Required Fields

Field	Description	Value
1.	Complete legal given (first) name of subject at birth	John
2.	Does the subject have a middle name?	No
3.	Complete additional (middle) name or names at birth	
4.	Complete legal family (last) name of subject at birth	Doe
5.	Day of birth [1-31]	4
6.	Month of birth	FEBRUARY
7.	Year of birth [####]	1974
8.	Name of city/municipality in which subject was born	Alabama
9.	Country of birth	UNITED STATES

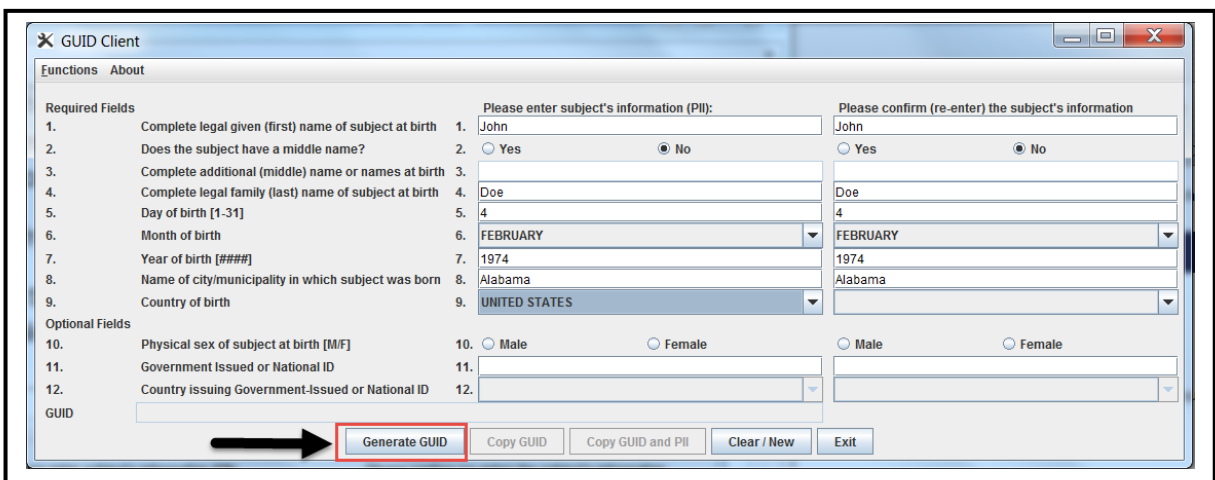
Optional Fields

Field	Description	Value
10.	Physical sex of subject at birth [M/F]	Male
11.	Government Issued or National ID	
12.	Country issuing Government-Issued or National ID	

GUID

Generate GUID Copy GUID Copy GUID and PII Clear / New Exit

7. Click the **Generate GUID** button. Note: Spaces, hyphens and apostrophes can be used in the non-numeric GUID fields in the dialog box and are stripped silently by the application



GUID Client

Functions About

Required Fields

Field	Description	Value
1.	Complete legal given (first) name of subject at birth	John
2.	Does the subject have a middle name?	No
3.	Complete additional (middle) name or names at birth	
4.	Complete legal family (last) name of subject at birth	Doe
5.	Day of birth [1-31]	4
6.	Month of birth	FEBRUARY
7.	Year of birth [####]	1974
8.	Name of city/municipality in which subject was born	Alabama
9.	Country of birth	UNITED STATES

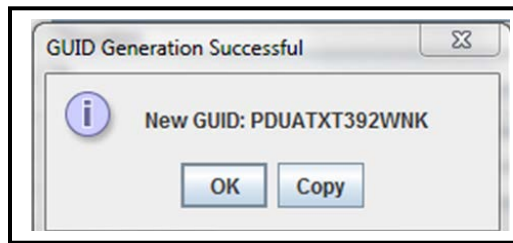
Optional Fields

Field	Description	Value
10.	Physical sex of subject at birth [M/F]	Male
11.	Government Issued or National ID	
12.	Country issuing Government-Issued or National ID	

GUID

Generate GUID Copy GUID Copy GUID and PII Clear / New Exit

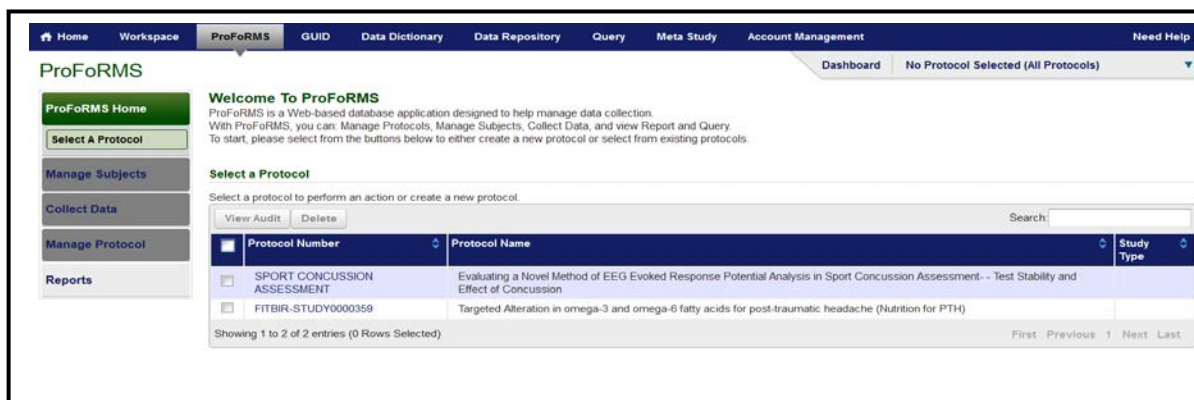
8. A popup window with the GUID information will appear if there was successful GUID generation. Click the **OK** button.



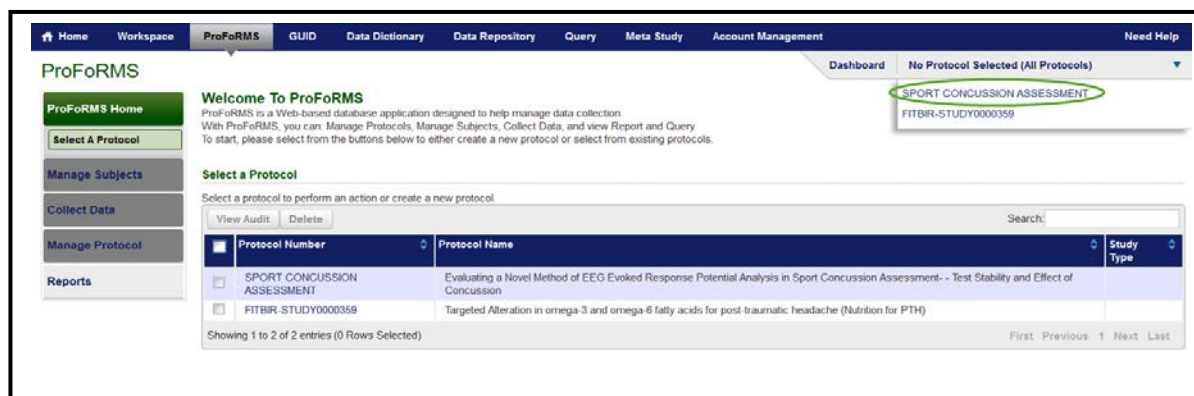
3.6.3 Edit Subject Information

To access this feature: Perform the following actions:

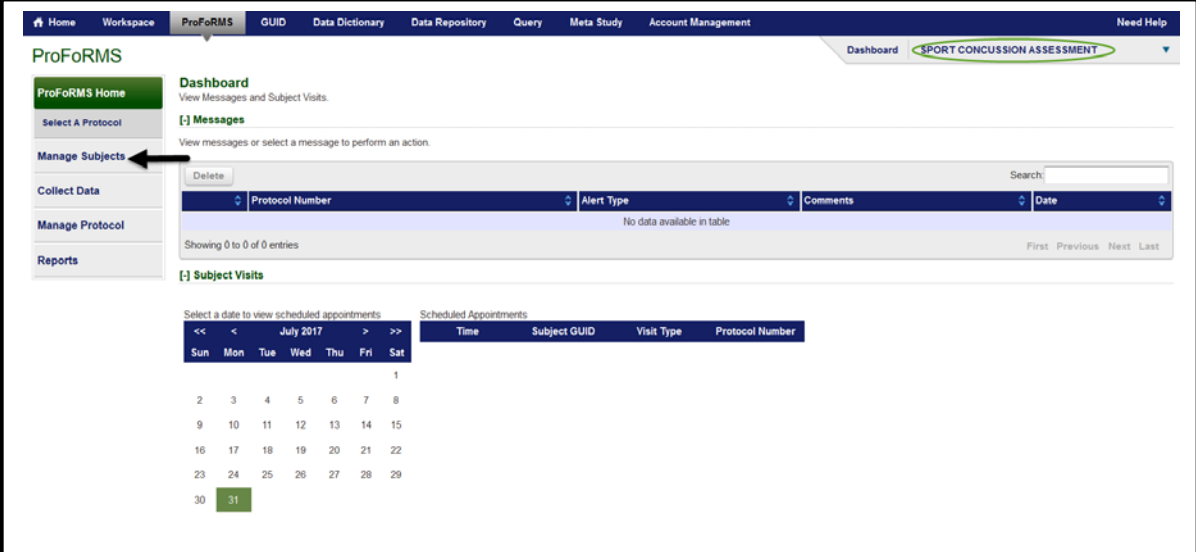
1. Navigate to the **ProFoRMS** module




2. Select a **Protocol** by using the drop-down menu located on the top right-hand.

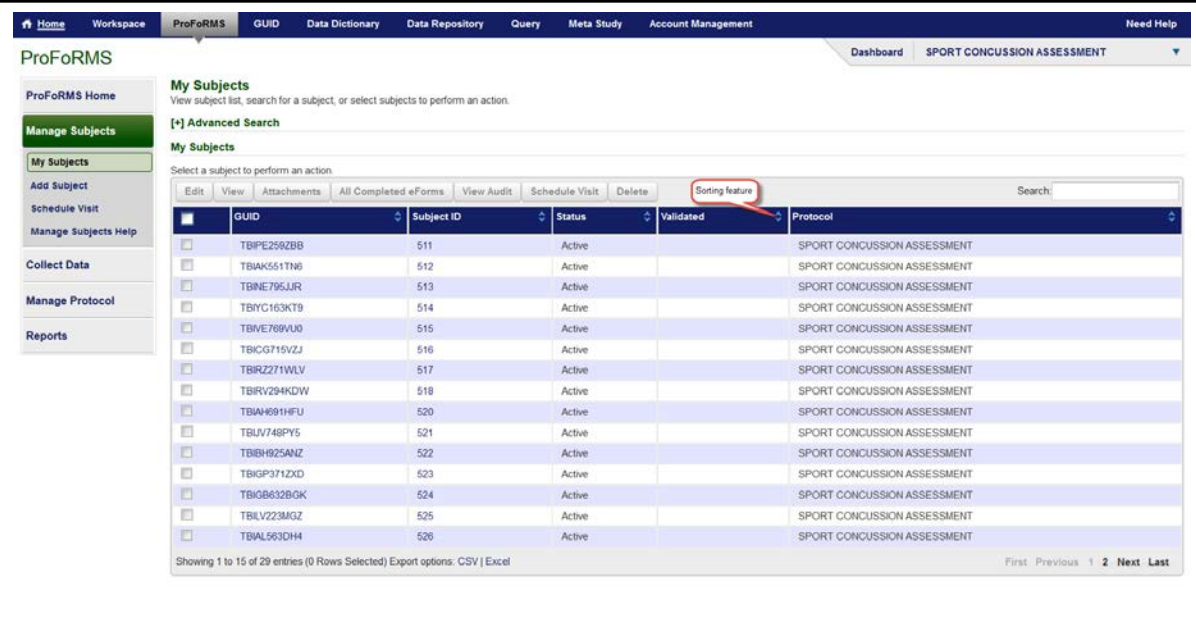


3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



The screenshot shows the ProFoRMS Dashboard. The left sidebar contains a 'Manage Subjects' link. The main content area has a 'Dashboard' section with a 'Messages' table (empty) and a 'Subject Visits' section with a calendar for July 2017.

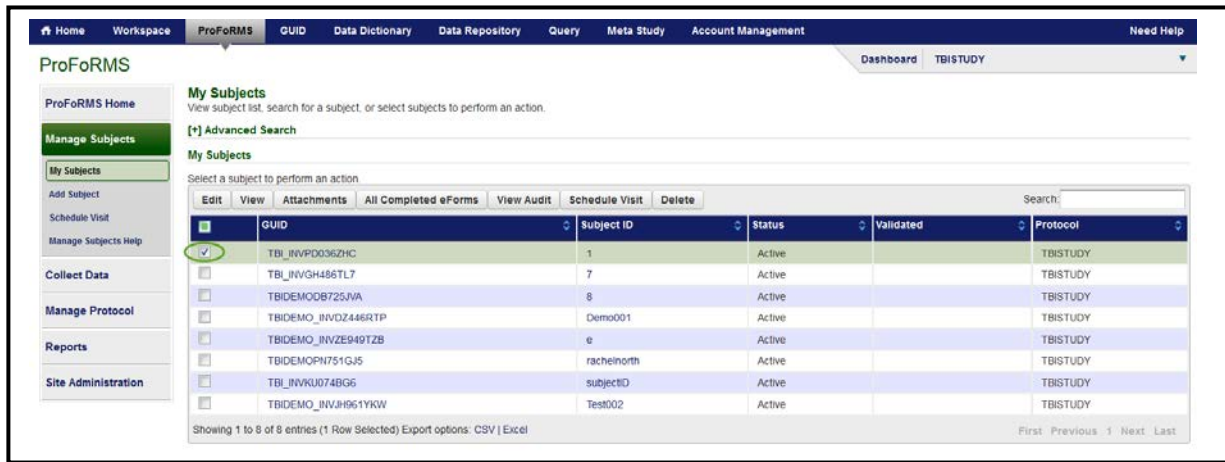
4. **My Subjects** page appears within a list that can be sorted by clicking on the arrows on any field using the  symbol. While in the Subject view, you may *View Subject lists*, *Search for Subject* or *Select Subjects* to perform any desired action.



The screenshot shows the 'My Subjects' page. The left sidebar has 'My Subjects' highlighted. The main content area shows a table of subjects. A red box highlights the 'Sorting feature' on the 'Validated' column header.

	GUID	Subject ID	Status	Validated	Protocol
<input type="checkbox"/>	TBPE259ZBB	511	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIAK551TN6	512	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBINE795JUR	513	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBYC163KT9	514	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIVE769VU0	515	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBICG715VZJ	516	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIRZ271WLW	517	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIRV294KDW	518	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIAH691HFU	520	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIJ7748PY5	521	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBBIH925ANZ	522	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIGP371ZKD	523	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBIGB632BGK	524	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBILV223MGZ	525	Active		SPORT CONCUSSION ASSESSMENT
<input type="checkbox"/>	TBALV563CH4	526	Active		SPORT CONCUSSION ASSESSMENT

5. Select a **Subject** from the list of subjects to edit.



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

My Subjects
View subject list, search for a subject, or select subjects to perform an action.

[*] Advanced Search

My Subjects
Select a subject to perform an action

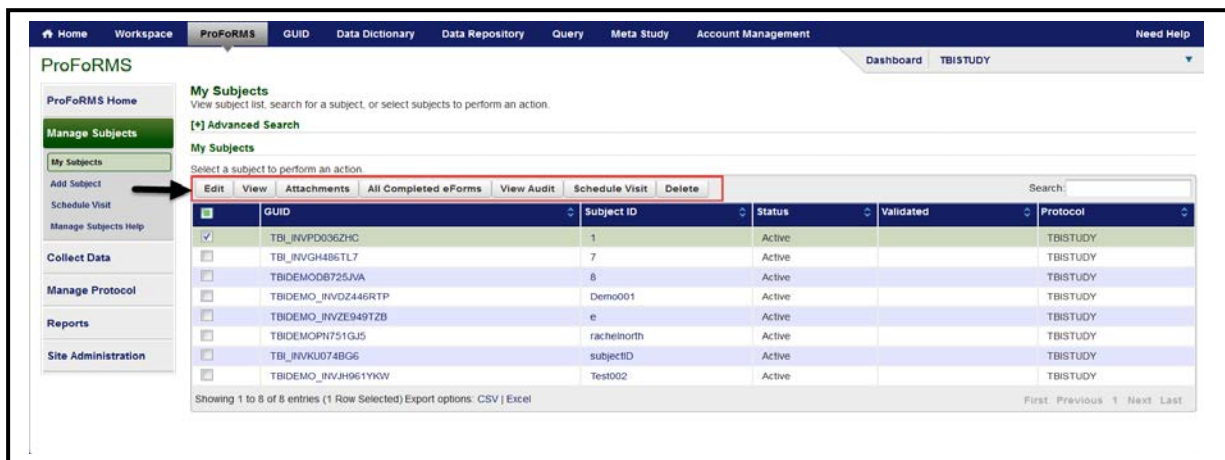
Edit View Attachments All Completed eForms View Audit Schedule Visit Delete Search:

	GUID	Subject ID	Status	Validated	Protocol
<input checked="" type="checkbox"/>	TBI_INVPO036ZHC	1	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVGH486TL7	7	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO08725JVA	8	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INV02446RTP	Demo001	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZE949TZB	e	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMOPN751GJ5	rachelnorth	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVJH061YKW	Test002	Active		TBISTUDY

Showing 1 to 8 of 8 entries (1 Row Selected) Export options: CSV | Excel

First Previous 1 Next Last

6. Click the **Edit** button from the action bar.



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

My Subjects
View subject list, search for a subject, or select subjects to perform an action.

[*] Advanced Search

My Subjects
Select a subject to perform an action

Edit View Attachments All Completed eForms View Audit Schedule Visit Delete Search:

	GUID	Subject ID	Status	Validated	Protocol
<input checked="" type="checkbox"/>	TBI_INVPO036ZHC	1	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVGH486TL7	7	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO08725JVA	8	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INV02446RTP	Demo001	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZE949TZB	e	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMOPN751GJ5	rachelnorth	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVJH061YKW	Test002	Active		TBISTUDY

Showing 1 to 8 of 8 entries (1 Row Selected) Export options: CSV | Excel

First Previous 1 Next Last

7. **NOTE:** Even though the link on the left hand side says "Add Subject," by clicking on the "Edit" button in the "My Subjects" page, it will bring the user to the "Edit Subject" page, where any required fields that was needed to create a subject (i.e. GUID or Pseudo-GUID, Protocol Subject ID) will already be populated.

ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

Edit Subject

Please enter subject information, add protocol information and other fields to add a subject.

[+] Subject Information

Mark subject data as Validated ☐

If the subject does not have a GUID or Pseudo-GUID created in the system, click on the "Create GUID" button below to launch the GUID Tool. The GUID Tool will allow you to enter the information necessary to generate a GUID or Pseudo-GUID for a subject. Once the GUID is generated, a pop-up will appear. The "Copy" button will copy the GUID to your clipboard so the generated ID can be pasted into the "GUID or Pseudo-GUID" text field in the Subject Information section. The "OK" button will exit the pop-up without saving the GUID to your clipboard; however, the generated ID can still be copied to your clipboard by clicking on the "Copy GUID" button on the GUID Tool.

Launch GUID Tool

* This symbol indicates a required field

GUID or Pseudo-GUID* TBI_INVPD03ZHC **VALID**

Additional Information Associated with Subject

Protocol Subject ID* 1 **Recruited** ☐

Biorepository Subject ID

[+] Protocol

Please enter protocol information

Associate Subject to Current Protocol ☐

Consent to Future Protocols ☐

Subject Number

Enrollment Date Format: YYYY-MM-DD

Subject Site NH or N/A

Completion Date Format: YYYY-MM-DD

Status in Current Protocol ☒ Active ☐ Inactive

[+] Attachments

Please make sure the attachment doesn't contain any PII.

Name*

Attachment*

Description

Category None

Add Cancel

Edit View Audit Delete

Search

Name	Description	Category
none	none	none

There are no attachments to display at this time.

Showing 1 to 1 of 1 entries

First Previous 1 Next Last

Save Reset Cancel

Subject Number

Enrollment Date Format: YYYY-MM-DD

Subject Site NH or N/A

Completion Date Format: YYYY-MM-DD

Status in Current Protocol ☒ Active ☐ Inactive

[+] Attachments

Please make sure the attachment doesn't contain any PII.

Name*

Attachment*

Description

Category None

Add Cancel

Edit View Audit Delete

Search

Name	Description	Category
none	none	none

There are no attachments to display at this time.

Showing 1 to 1 of 1 entries

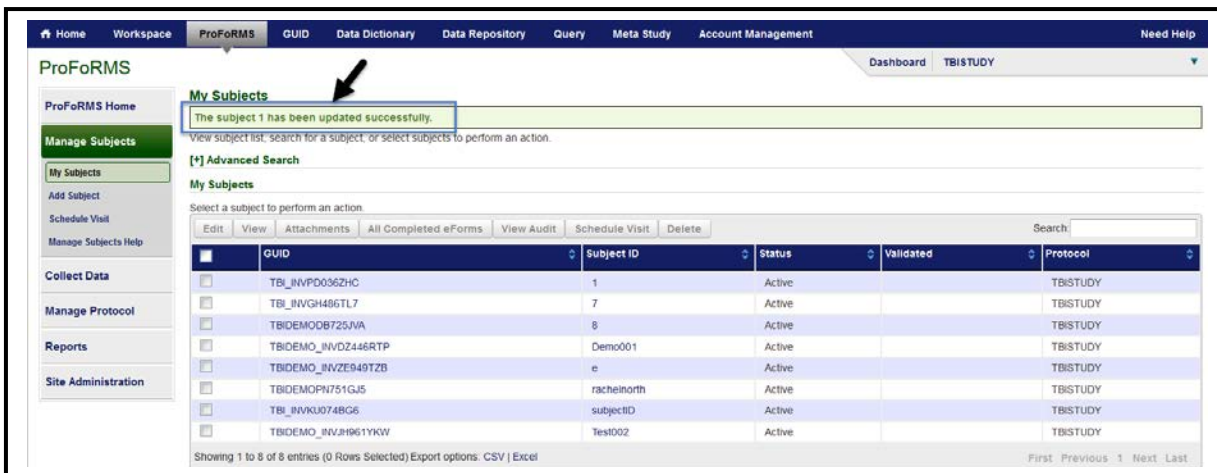
First Previous 1 Next Last

Save Reset Cancel

Document Attachment feature

Save

8. The **My Subject** page appears with at confirmation of the changes.



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

My Subjects

The subject 1 has been updated successfully.

View subject list, search for a subject, or select subjects to perform an action.

[*] Advanced Search

My Subjects

Select a subject to perform an action.

Edit View Attachments All Completed eForms View Audit Schedule Visit Delete Search

	GUID	Subject ID	Status	Validated	Protocol
<input type="checkbox"/>	TBI_INVPO036ZHC	1	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVGH486TL7	7	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO08725JVA	8	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INV02446RTP	Demo001	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZE949TZB	e	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMOPN751GJ5	racheinorth	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVKU0748G6	subjectID	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVJH961YKW	Test002	Active		TBISTUDY

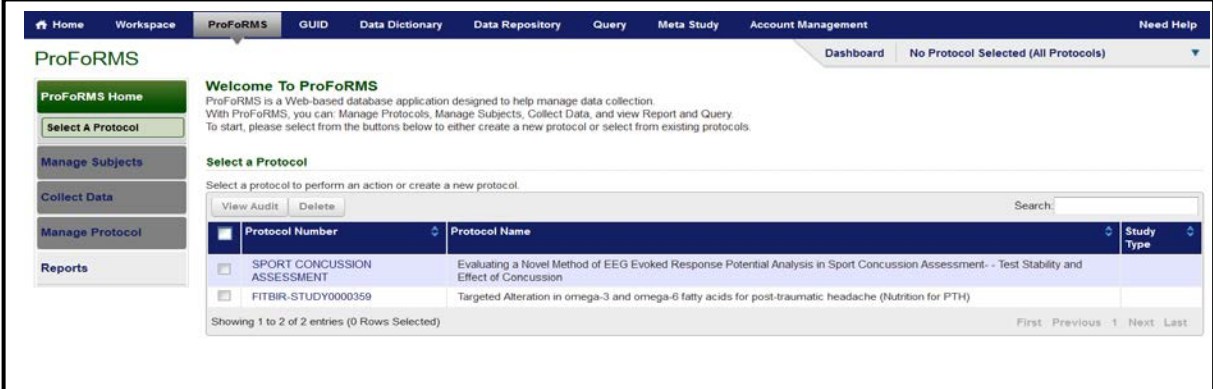
Showing 1 to 8 of 8 entries (0 Rows Selected) Export options: CSV | Excel

First Previous 1 Next Last

3.6.4 View Subject Information

To View Subject Information: Perform the following actions:

1. Navigate to the **ProFoRMS** module



ProFoRMS

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

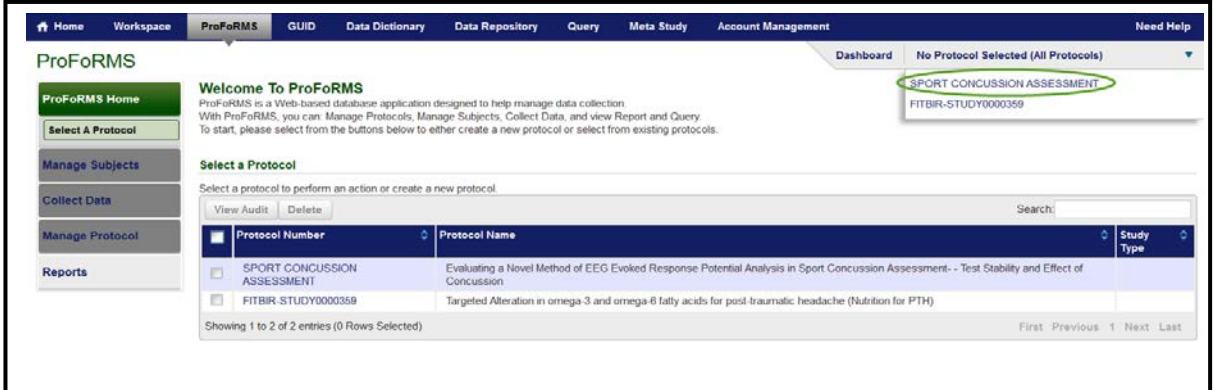
Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



ProFoRMS

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

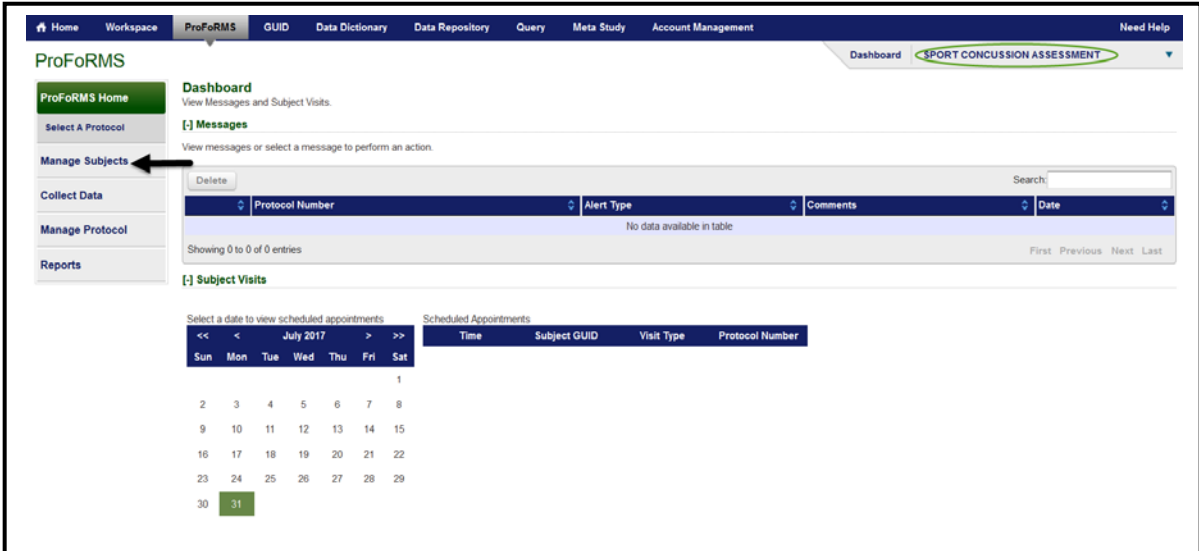
Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



ProFoRMS

Dashboard

View Messages and Subject Visits.

Messages

View messages or select a message to perform an action.

Delete Search:

Protocol Number	Alert Type	Comments	Date
No data available in table			


Showing 0 to 0 of 0 entries First Previous Next Last

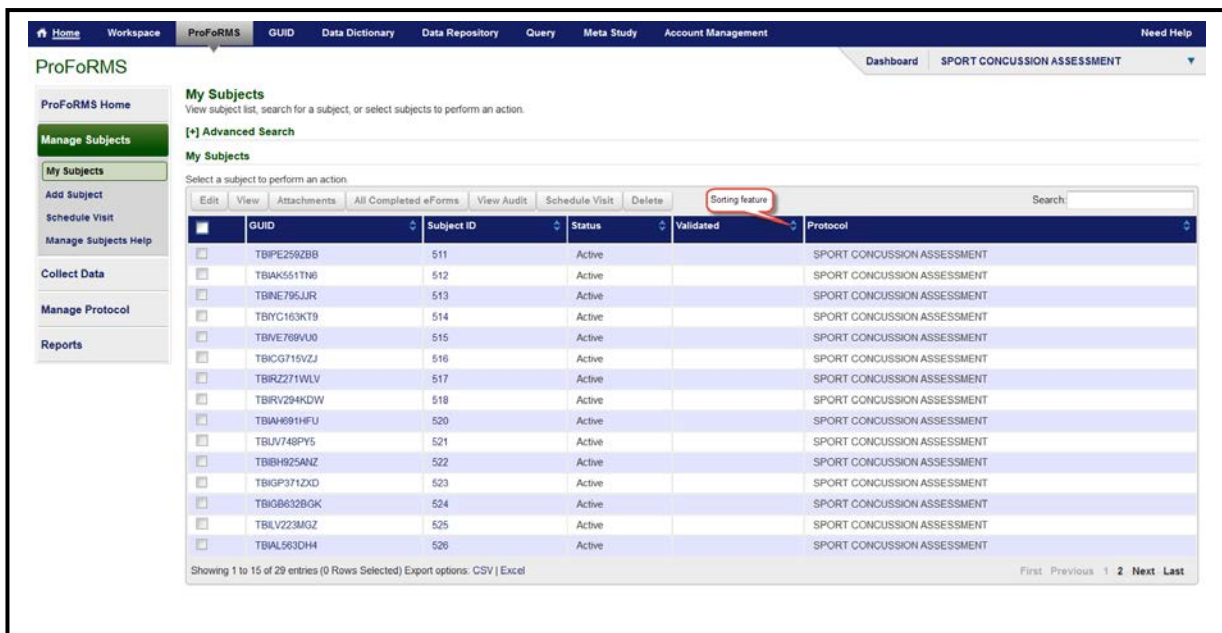
Subject Visits

Select a date to view scheduled appointments

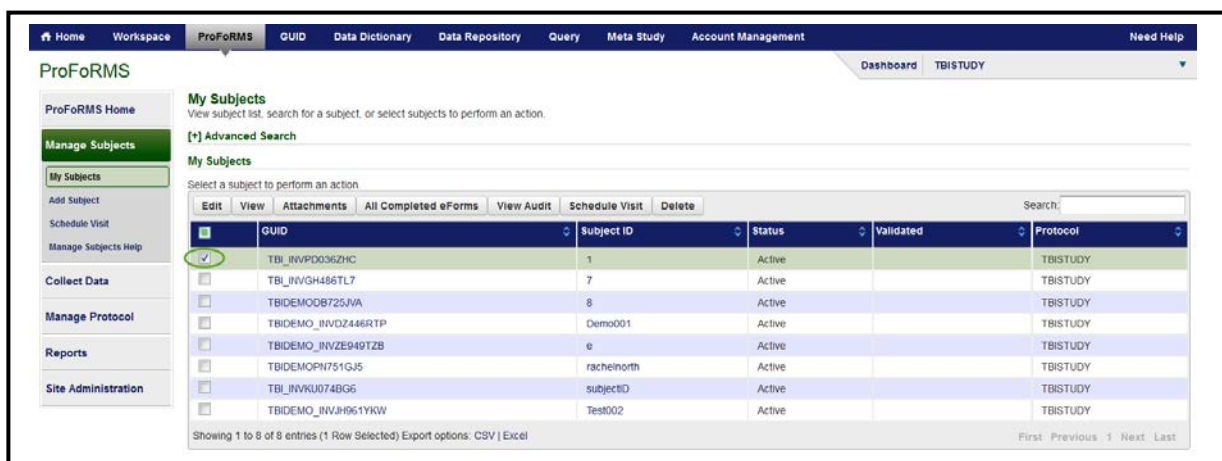
Scheduled Appointments

Time	Subject GUID	Visit Type	Protocol Number
<div> <div><< < July 2017 > >></div> <div> <div>Sun Mon Tue Wed Thu Fri Sat</div> <div> <div>1</div> <div>2 3 4 5 6 7 8</div> <div>9 10 11 12 13 14 15</div> <div>16 17 18 19 20 21 22</div> <div>23 24 25 26 27 28 29</div> <div>30 31</div> </div> </div> </div>			

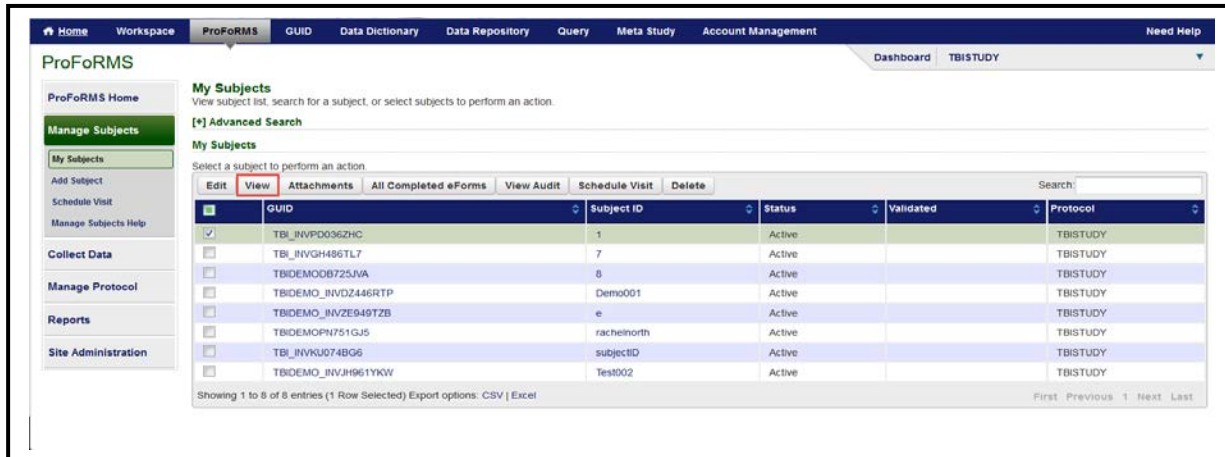
4. **My Subjects** page appears with in a list that can be sorted by clicking on the arrows on any field using the  symbol. While in the Subject view, you may *View Subject lists*, *Search for Subject* or *Select Subjects* to perform any desired action.



5. Select a **Subject** from the list of subjects to edit.



6. Click the **View** button from the action bar.



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

My Subjects

View subject list. Search for a subject, or select subjects to perform an action.

[*] Advanced Search

Select a subject to perform an action.

Edit View Attachments All Completed eForms View Audit Schedule Visit Delete Search:

	GUID	Subject ID	Status	Validated	Protocol
<input checked="" type="checkbox"/>	TBI_INVPO036ZHC	1	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVGH486TL7	7	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO08725JVA	8	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INV02446RTP	Demo001	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INV2E949TZB	e	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMOPN751GU5	rachelnorth	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVJH961YKV	Test002	Active		TBISTUDY

Showing 1 to 8 of 8 entries (1 Row Selected) Export options: CSV | Excel

First Previous 1 Next Last

- The View Subject Information appears showing the various sections: Subject Information, Protocol, Scheduled Visits, Attachments and Completed eForms.

Home
Workspace
ProFoRMS
GUID
Data Dictionary
Data Repository
Query
Meta Study
Account Management
Need Help

Dashboard
TBISTUDY

ProFoRMS Home
Manage Subjects
My Subjects
Add Subject
Schedule Visit
Manage Subjects Help
Collect Data
Manage Protocol
Reports
Site Administration

View Subject:

View subject information or select a section to edit.

[-] Subject Information

Mark subject data as Validated
GUID or Pseudo-GUID TBI_INVPD006ZHC
Protocol Subject ID 1
Biorepository Subject ID
Recruit

[-] Protocol

Associate Subject to Current Protocol
Subject Number
Enrollment Date
Completion Date
Consent to Future Protocols
Protocol Subject ID 1
Subject Site N.A.
Status in Current Protocol Active Inactive

[-] Scheduled Visits

Date and Time	Visit Type
2013-07-29 14:45	Baseline Visit
2016-04-28 13:20	Baseline Visit
2016-10-03 00:00	Baseline Visit
2016-10-30 00:00	Baseline Visit
2017-01-26 16:06	Baseline Visit
2017-04-04 05:13	Follow up 36 months
2017-04-05 13:29	HIT 6 Mod again
2018-01-26 15:50	Baseline Visit

[-] Attachments

Name	Description	Category
No data available in table		

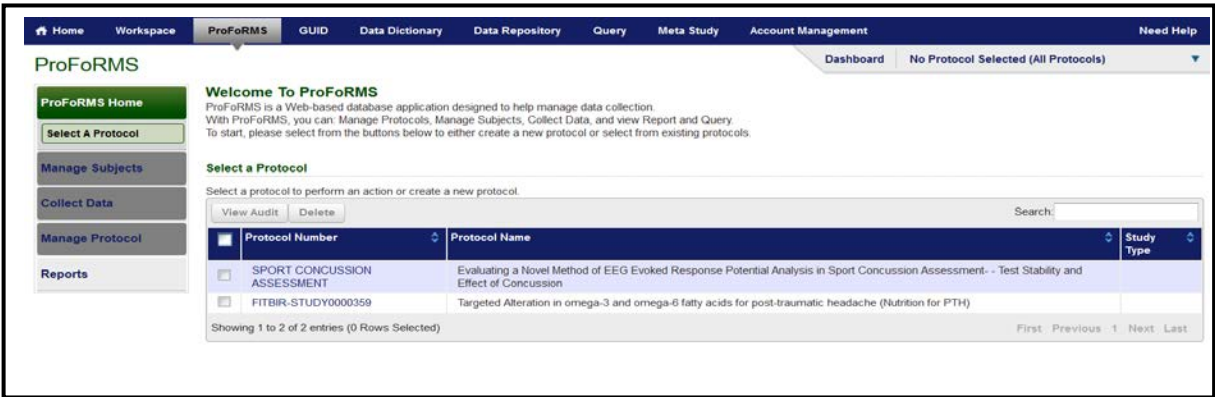
[-] Completed eForms

Form Name	Completed Date and Time
Multi Select Test 2	2014-06-12 10:10
-	2017-01-26 19:42
June24th2016	2016-06-24 16:49
JO*	2017-01-26 19:42
Exam_EE	2017-01-26 19:40

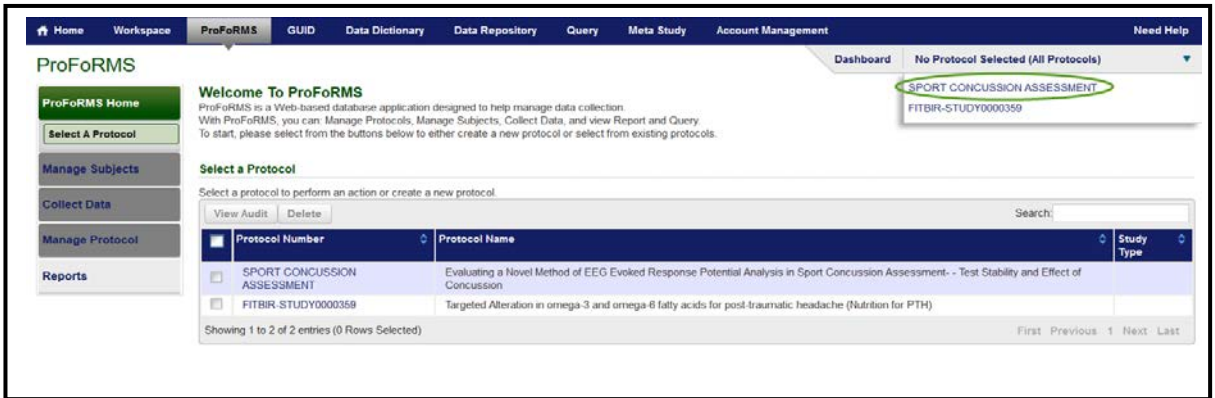
3.6.5 Scheduling Visits

To Schedule a visit: Perform the following actions:

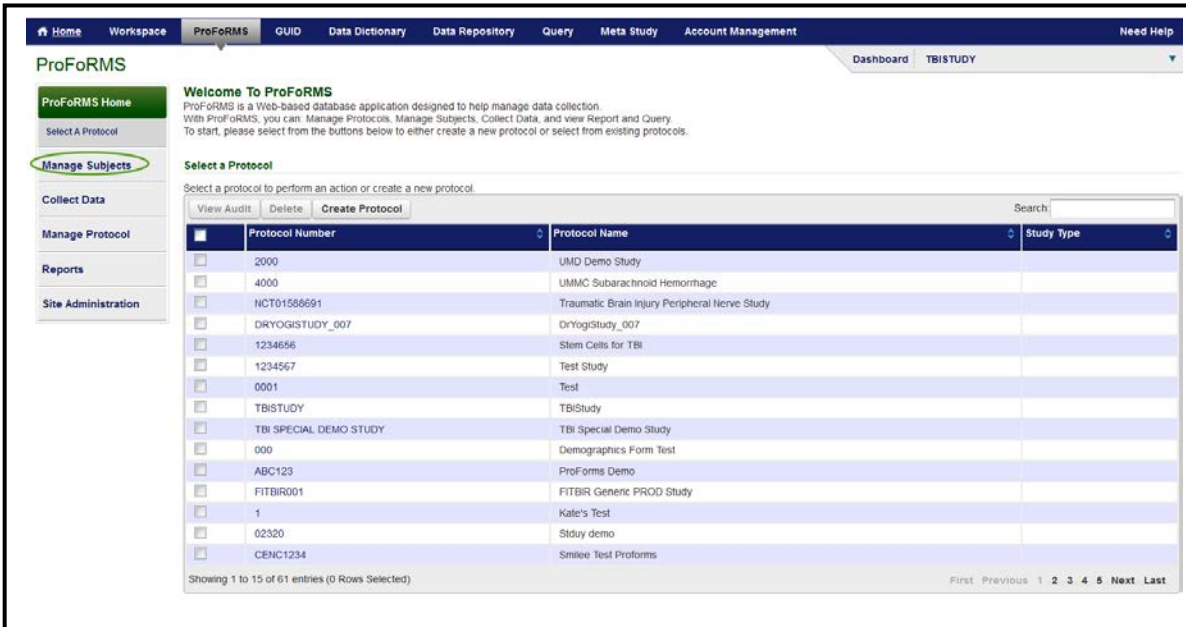
- 1. Navigate to the **ProFoRMS** module



- 2. Select a **Protocol** by using the drop-down menu located on the top right-hand.




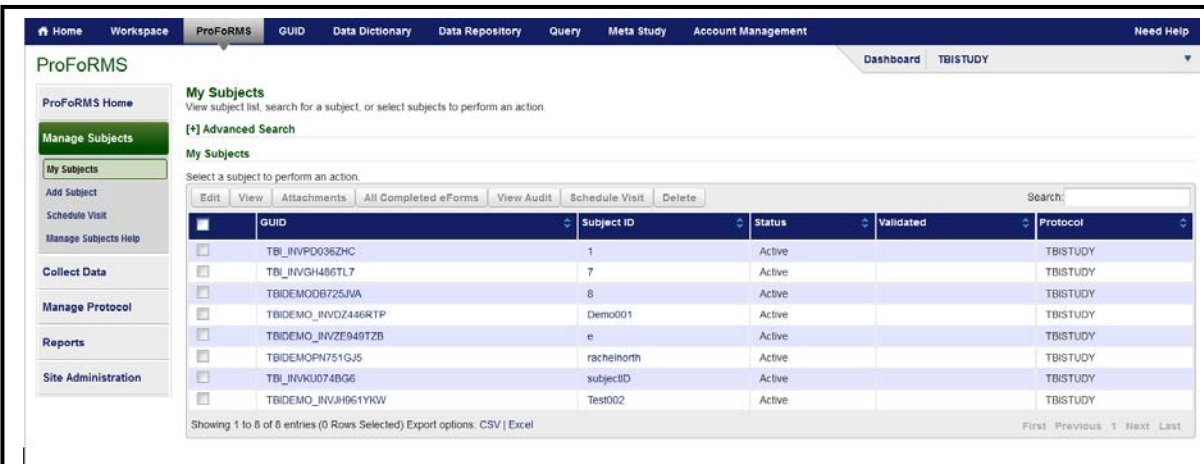
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



The screenshot shows the ProFoRMS Dashboard. The left sidebar has a green button labeled 'Manage Subjects' which is circled in red. The main content area shows a 'Welcome To ProFoRMS' message and a 'Select a Protocol' section with a table of protocols.

Protocol Number	Protocol Name	Study Type
2000	UMD Demo Study	
4000	UMMC Subarachnoid Hemorrhage	
NCT01586691	Traumatic Brain Injury Peripheral Nerve Study	
DRYOGISTUDY_007	DRYOGISTUDY_007	
1234656	Stem Cells for TBI	
1234567	Test Study	
0001	Test	
TBISTUDY	TBISTudy	
TBI SPECIAL DEMO STUDY	TBI Special Demo Study	
000	Demographics Form Test	
ABC123	ProForms Demo	
FITBIR001	FITBIR Genetic PROD Study	
1	Kate's Test	
02320	Study demo	
CENC1234	Smilee Test Protforms	

4. My Subjects page appears with in a list that can be sorted by clicking on the arrows on any field using the  symbol.

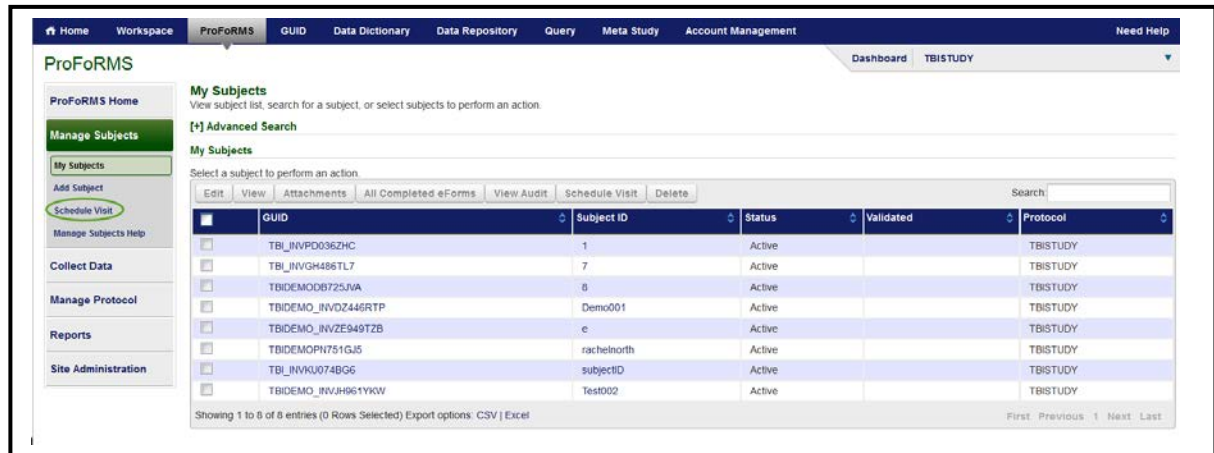


The screenshot shows the 'My Subjects' page. The left sidebar has a green button labeled 'My Subjects' which is highlighted. The main content area shows a 'My Subjects' section with a table of subjects.

GUID	Subject ID	Status	Validated	Protocol
TBI_INVPO036ZHC	1	Active		TBISTUDY
TBI_INVGH486TL7	7	Active		TBISTUDY
TBIDEMO08725JJA	8	Active		TBISTUDY
TBIDEMO_INVZ446RTP	Demo001	Active		TBISTUDY
TBIDEMO_INVZE949TZB	e	Active		TBISTUDY
TBIDEMOPN751GJ5	rachelnorth	Active		TBISTUDY
TBI_INVKU074BG6	subjectID	Active		TBISTUDY
TBIDEMO_INVJH661YKW	Test002	Active		TBISTUDY

NOTE: You may also be able to schedule a visit for a specific subject by going to "My Subjects" page, selecting subject by clicking on the checkbox (this will enable numerous buttons such as edit, view, etc.), then select "Schedule Visit" button. This will direct you to the "Schedule Visit" page, with the GUID/Pseudo-GUID that was selected prepopulated in the GUID/Pseudo-GUID field.

5. Click the **Schedule Visit** tab on the left-side tool bar.



ProFoRMS

My Subjects
View subject list, search for a subject, or select subjects to perform an action.

[*] Advanced Search

My Subjects
Select a subject to perform an action.

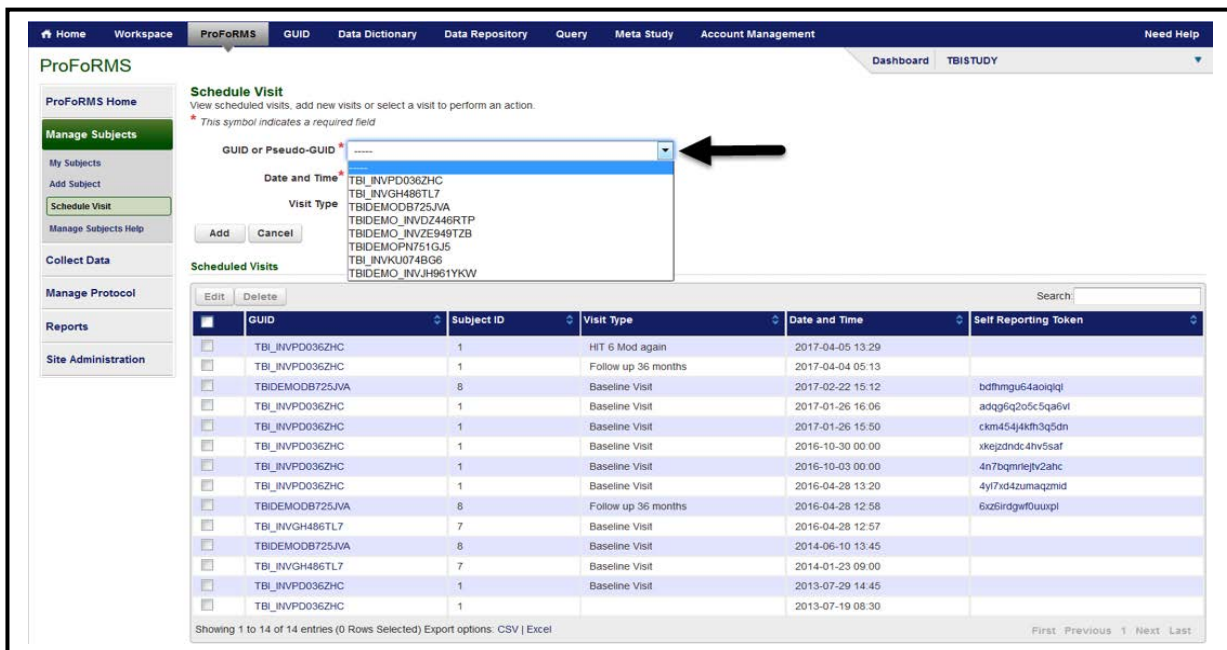
Edit View Attachments All Completed eForms View Audit Schedule Visit Delete Search

	GUID	Subject ID	Status	Validated	Protocol
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVG486TL7	7	Active		TBISTUDY
<input type="checkbox"/>	TBIEMOD8725JVA	8	Active		TBISTUDY
<input type="checkbox"/>	TBIEMO_INVZ446RTP	Demo001	Active		TBISTUDY
<input type="checkbox"/>	TBIEMO_INVZE949TZB	e	Active		TBISTUDY
<input type="checkbox"/>	TBIEMOPN751GJ5	rachelnorth	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Active		TBISTUDY
<input type="checkbox"/>	TBIEMO_INVJH961YKW	Test002	Active		TBISTUDY

Showing 1 to 8 of 8 entries (0 Rows Selected) Export options: CSV | Excel

First Previous 1 Next Last

6. Select the **GUID or Pseudo-GUID** of the Subject you would like to schedule a visit from the GUID or Pseudo-GUID drop-down menu.



ProFoRMS

Schedule Visit
View scheduled visits, add new visits or select a visit to perform an action.
* This symbol indicates a required field

GUID or Pseudo-GUID *

Date and Time *

Visit Type

Add Cancel


Scheduled Visits

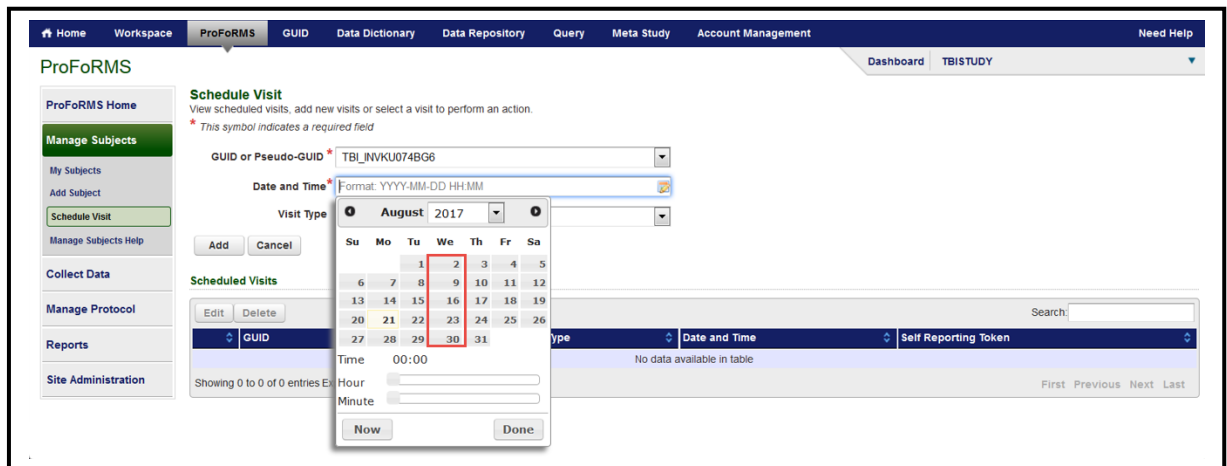
Edit Delete Search

	GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
<input type="checkbox"/>	TBI_INVPD036ZHC	1	HIT 6 Mod again	2017-04-05 13:29	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Follow up 36 months	2017-04-04 05:13	
<input type="checkbox"/>	TBIEMOD8725JVA	8	Baseline Visit	2017-02-22 15:12	bdfhmgus4a0iqiqi
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 16:06	adqg6q2o5c5qa6v
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 15:50	ckm454j4kh3q5dn
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-30 00:00	xkejdndc4nv5saf
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqmriejv2ahc
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-04-28 13:20	4yl7xd4zumaqzmid
<input type="checkbox"/>	TBIEMOD8725JVA	8	Follow up 36 months	2016-04-28 12:58	6xz5irdgwf0uuxpi
<input type="checkbox"/>	TBI_INVG486TL7	7	Baseline Visit	2016-04-28 12:57	
<input type="checkbox"/>	TBIEMOD8725JVA	8	Baseline Visit	2014-06-10 13:45	
<input type="checkbox"/>	TBI_INVG486TL7	7	Baseline Visit	2014-01-23 09:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2013-07-29 14:45	
<input type="checkbox"/>	TBI_INVPD036ZHC	1		2013-07-19 08:30	

Showing 1 to 14 of 14 entries (0 Rows Selected) Export options: CSV | Excel

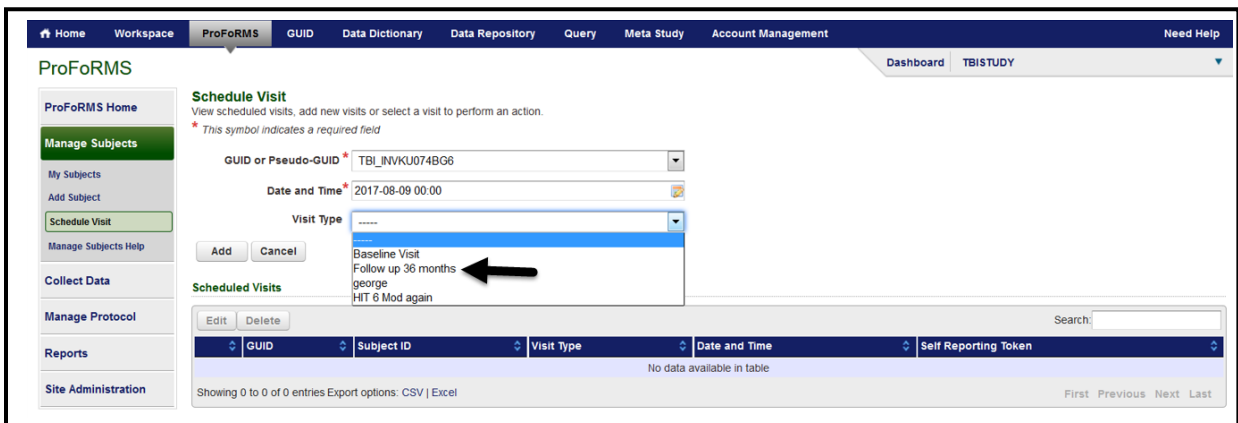
First Previous 1 Next Last

7. Click the **Calendar**  icon to choose the desired **Date** and **Time** for the visit.



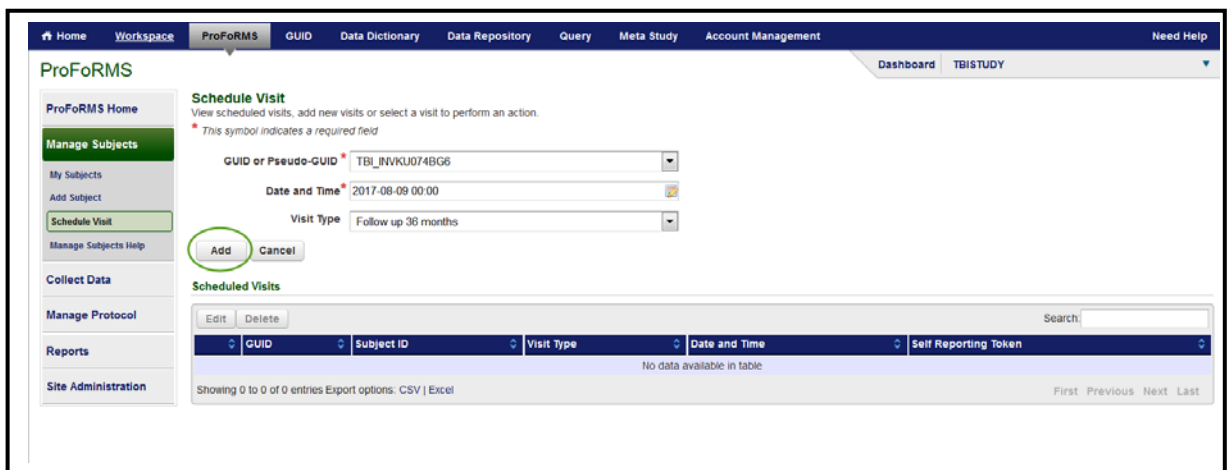
The screenshot shows the 'Schedule Visit' form in the ProFoRMS application. The 'GUID or Pseudo-GUID' field contains 'TBI_INVKU074BG6'. The 'Date and Time' field is open, displaying a calendar for August 2017. The date '29' is highlighted. The 'Visit Type' dropdown is set to 'GUID'. The 'Add' button is visible. The 'Scheduled Visits' table is empty, showing 'No data available in table'.

8. Choose the **Visit Type** from the drop-down menu.



The screenshot shows the 'Schedule Visit' form with the 'Visit Type' dropdown menu open. The options are 'Baseline Visit', 'Follow up 36 months', 'george', and 'HIT 6 Mod again'. An arrow points to the 'Follow up 36 months' option. The 'Date and Time' field is set to '2017-08-09 00:00'. The 'Add' button is visible. The 'Scheduled Visits' table is empty, showing 'No data available in table'.

9. Click the **Add** button.



The screenshot shows the 'Schedule Visit' form with the 'Add' button circled in green. The 'Visit Type' dropdown is set to 'Follow up 36 months'. The 'Date and Time' field is set to '2017-08-09 00:00'. The 'Add' button is visible. The 'Scheduled Visits' table is empty, showing 'No data available in table'.


10. The newly scheduled visit will be displayed on the Scheduled Visits list as shown below:


Edit Delete		Search:			
	GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Follow up 36 months	2017-08-09 00:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	HiT 6 Mod again	2017-04-05 13:29	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Follow up 36 months	2017-04-04 05:13	
<input type="checkbox"/>	TBIDEMOD8725JVA	8	Baseline Visit	2017-02-22 15:12	bdthmgu64aoiqi
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 16:06	adqg6q2o5c5qa6vi
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 15:50	ckm454j4kfh3q5dn
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-30 00:00	xkejdndc4hv5saf
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqmrlejt2ahc
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-04-28 13:20	4yif7xd4zumaqzmid
<input type="checkbox"/>	TBIDEMOD8725JVA	8	Follow up 36 months	2016-04-28 12:58	6xz6irdgwf0uuxpi
<input type="checkbox"/>	TBI_INVGH486TL7	7	Baseline Visit	2016-04-28 12:57	
<input type="checkbox"/>	TBIDEMOD8725JVA	8	Baseline Visit	2014-06-10 13:45	
<input type="checkbox"/>	TBI_INVGH486TL7	7	Baseline Visit	2014-01-23 09:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2013-07-29 14:45	
<input type="checkbox"/>	TBI_INVPD036ZHC	1		2013-07-19 08:30	

Showing 1 to 15 of 15 entries (0 Rows Selected) Export options: CSV | Excel

First Previous 1 Next Last


ICON KEY

 Notes


 Important


Information


Things to Note:


 Another pathway to scheduling a visit:

 Go to **My Subject**

 Select any GUID by clicking on the checkbox

 Click the Schedule Visit button, which will be activated once a GUID is selected

 This action will bring the user to the Schedule Visit page where you can schedule a visit

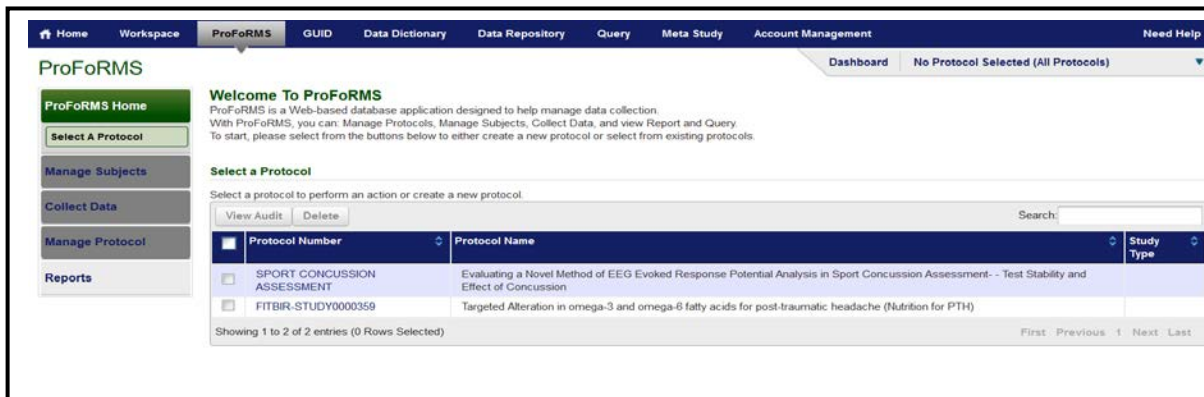
 This step is recommended as the User can search/filter for a specific GUID through the search bar instead of finding the GUID using the drop down-menu.

3.6.6 Editing Scheduled Visits

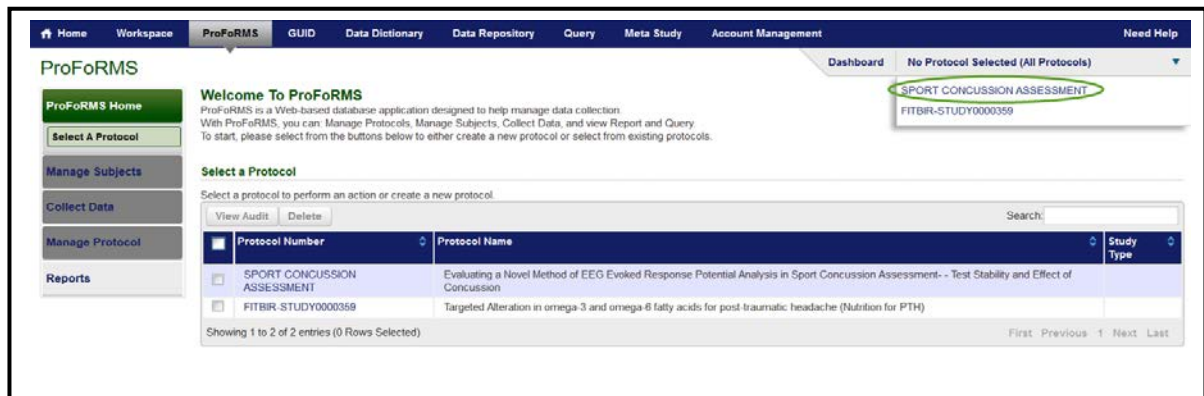
The **Schedule Visits** feature provides you with the ability to schedule visits as well as perform other functions such as **Edit Visits**, **Delete Visits**.

To edit scheduled visits: Perform the following actions:

1. Click the **ProFoRMS** tab at the top of the screen



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TBISTUDY

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Site Administration

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.


Select a Protocol

Select a protocol to perform an action or create a new protocol.

View AuditDeleteCreate Protocol

	Protocol Number	Protocol Name	Study Type
<input type="checkbox"/>	2000	UMD Demo Study	
<input type="checkbox"/>	4000	UMAC Subarachnoid Hemorrhage	
<input type="checkbox"/>	NCT01585691	Traumatic Brain Injury Peripheral Nerve Study	
<input type="checkbox"/>	DRYOGISTUDY_007	DRYogistudy_007	
<input type="checkbox"/>	1234656	Stem Cells for TBI	
<input type="checkbox"/>	1234567	Test Study	
<input type="checkbox"/>	0001	Test	
<input type="checkbox"/>	TBISTUDY	TBISTudy	
<input type="checkbox"/>	TBI SPECIAL DEMO STUDY	TBI Special Demo Study	
<input type="checkbox"/>	000	Demographics Form Test	
<input type="checkbox"/>	AIRC123	ProForms Demo	
<input type="checkbox"/>	FITBIR001	FITBIR Generic PROD Study	
<input type="checkbox"/>	1	Kate's Test	
<input type="checkbox"/>	02320	Stduy demo	
<input type="checkbox"/>	CENC1234	Smilee Test Protforms	

Showing 1 to 15 of 61 entries (0 Rows Selected)First Previous 1 2 3 4 5 Next Last

4. My Subjects page appears with in a list that can be sorted by clicking on the arrows on any field using the  symbol.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TBISTUDY

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

My Subjects

View subject list, search for a subject, or select subjects to perform an action

[*] Advanced Search

My Subjects

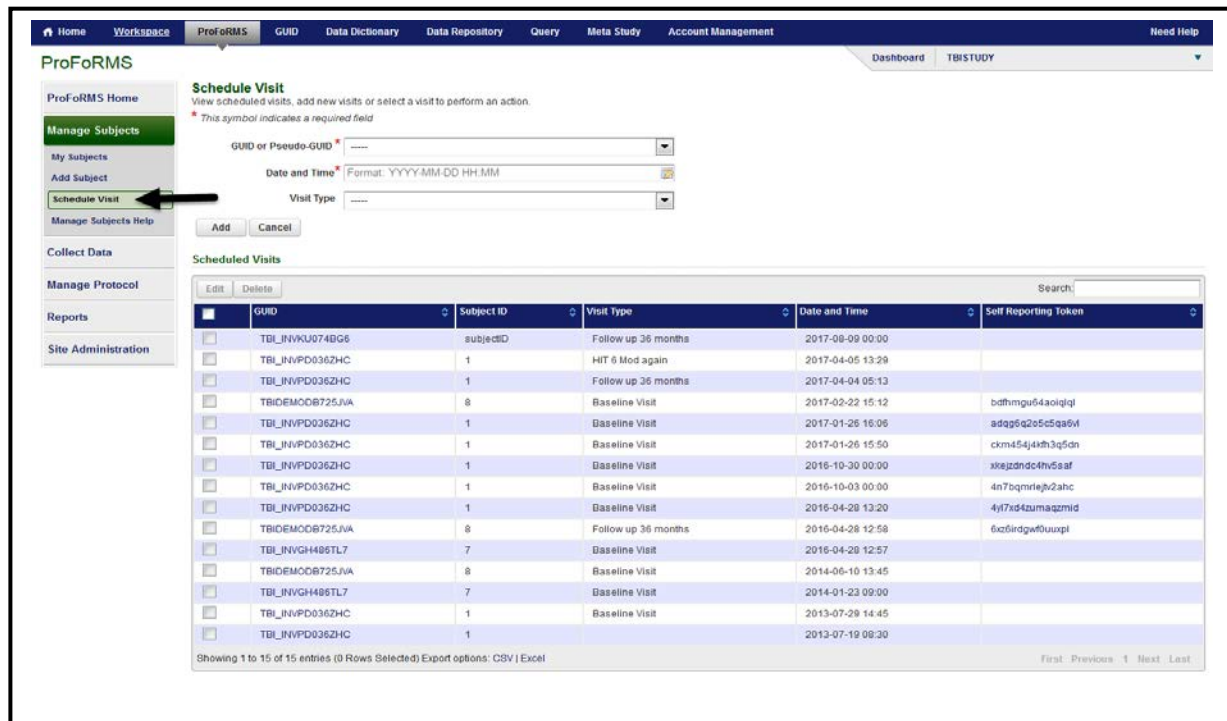
Select a subject to perform an action.

EditViewAttachmentsAll Completed eFormsView AuditSchedule VisitDelete

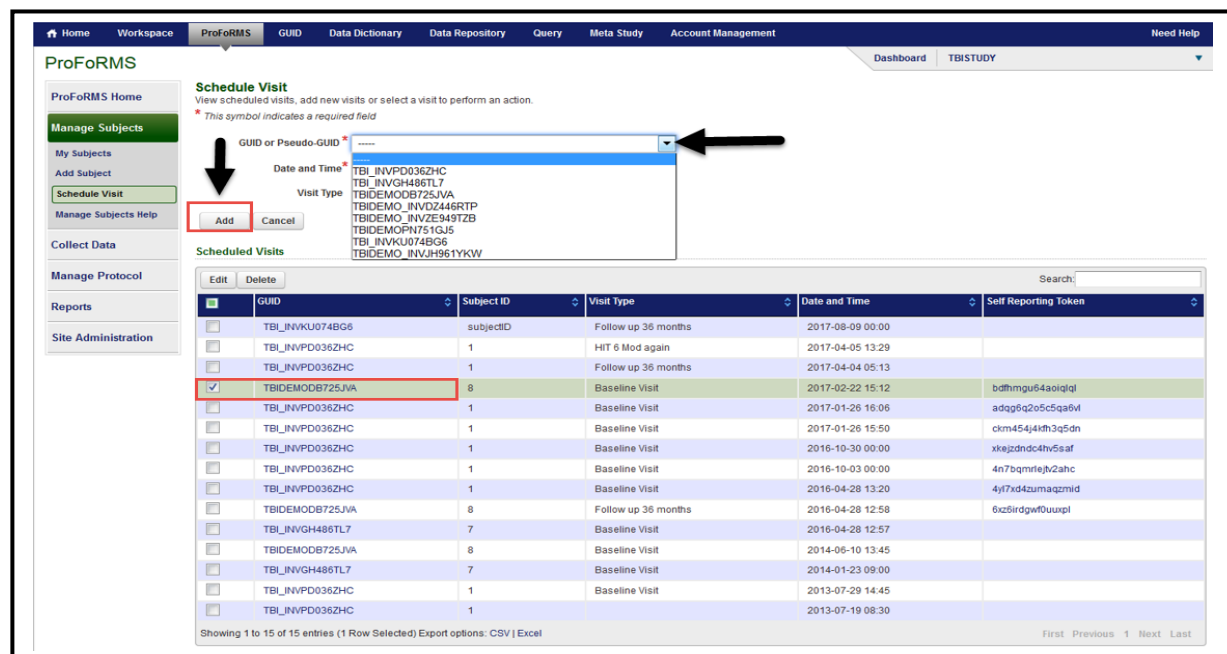
	GUID	Subject ID	Status	Validated	Protocol
<input type="checkbox"/>	TBI_INVPO36ZHC	1	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVGH486TL7	7	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO08725JVA	8	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZ446RTP	Demo001	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZE949TZB	e	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMOPN751GJ5	racheinorth	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVH061YKW	Test002	Active		TBISTUDY

Showing 1 to 6 of 6 entries (0 Rows Selected) Export options: CSV | ExcelFirst Previous 1 Next Last

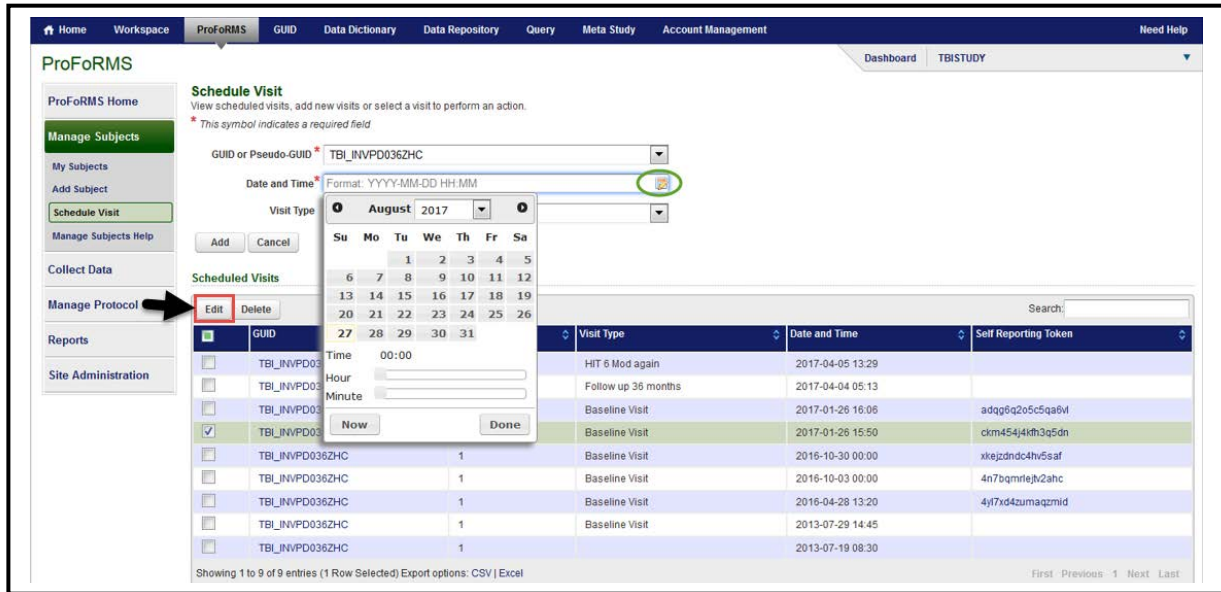
5. Click the **Schedule Visit** tab on the left-side tool bar.



6. The **Schedule Visit** page appears from where you can *View Scheduled Visits*, *Add New View Visits*, or *Select a Visit* to perform an action. Select the **GUID** of the Subject you would like to schedule a visit from the **GUID or Pseudo-GUID** drop-down menu.



- Click on the **Edit** button to update as needed. Using the **Calendar**  icon to choose the desired **Date** and **Time** for the visit



ProFoRMS

Schedule Visit
View scheduled visits, add new visits or select a visit to perform an action.
* This symbol indicates a required field

GUID or Pseudo-GUID: TBL_INVPD036ZHC

Date and Time: Format: YYYY-MM-DD HH.MM

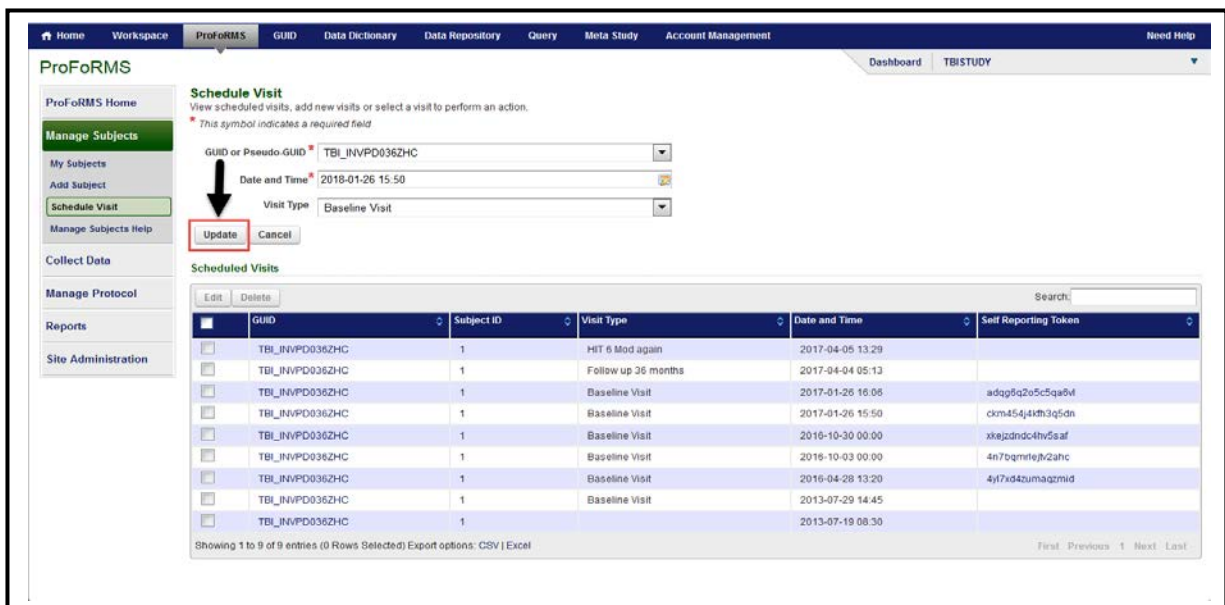
Visit Type: Baseline Visit

SCHEDULED VISITS

GUID	Time	Visit Type	Date and Time	Self Reporting Token
TBL_INVPD036ZHC	00:00	HIT 6 Mod again	2017-04-05 13:29	
TBL_INVPD036ZHC		Follow up 36 months	2017-04-04 05:13	
TBL_INVPD036ZHC		Baseline Visit	2017-01-26 16:06	adqg9q2o5c5qa8vl
TBL_INVPD036ZHC		Baseline Visit	2017-01-26 15:50	ckm454j4kh3q5dn
TBL_INVPD036ZHC	1	Baseline Visit	2016-10-30 00:00	xkejdndc4hv5saf
TBL_INVPD036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqmiejh2ahc
TBL_INVPD036ZHC	1	Baseline Visit	2016-04-28 13:20	4yl7xd4zmagzmid
TBL_INVPD036ZHC	1	Baseline Visit	2013-07-29 14:45	
TBL_INVPD036ZHC	1	Baseline Visit	2013-07-19 08:30	

Showing 1 to 9 of 9 entries (1 Row Selected) Export options: CSV | Excel

- Click the **Update** button to complete the edit action.



ProFoRMS

Schedule Visit
View scheduled visits, add new visits or select a visit to perform an action.
* This symbol indicates a required field

GUID or Pseudo-GUID: TBL_INVPD036ZHC

Date and Time: 2018-01-26 15:50

Visit Type: Baseline Visit

SCHEDULED VISITS

GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
TBL_INVPD036ZHC	1	HIT 6 Mod again	2017-04-05 13:29	
TBL_INVPD036ZHC	1	Follow up 36 months	2017-04-04 05:13	
TBL_INVPD036ZHC	1	Baseline Visit	2017-01-26 16:06	adqg9q2o5c5qa8vl
TBL_INVPD036ZHC	1	Baseline Visit	2017-01-26 15:50	ckm454j4kh3q5dn
TBL_INVPD036ZHC	1	Baseline Visit	2016-10-30 00:00	xkejdndc4hv5saf
TBL_INVPD036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqmiejh2ahc
TBL_INVPD036ZHC	1	Baseline Visit	2016-04-28 13:20	4yl7xd4zmagzmid
TBL_INVPD036ZHC	1	Baseline Visit	2013-07-29 14:45	
TBL_INVPD036ZHC	1	Baseline Visit	2013-07-19 08:30	

Showing 1 to 9 of 9 entries (0 Rows Selected) Export options: CSV | Excel

9. The newly scheduled visit will be displayed on the Scheduled Visits list as shown below:

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help
Dashboard TBISTUDY

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

Schedule Visit

The scheduled visit has been updated successfully.

View scheduled visits, add new visits or select a visit to perform an action.

* This symbol indicates a required field

GUID or Pseudo GUID *

Date and Time *

Visit Type *

Scheduled Visits

Edit Delete
Search

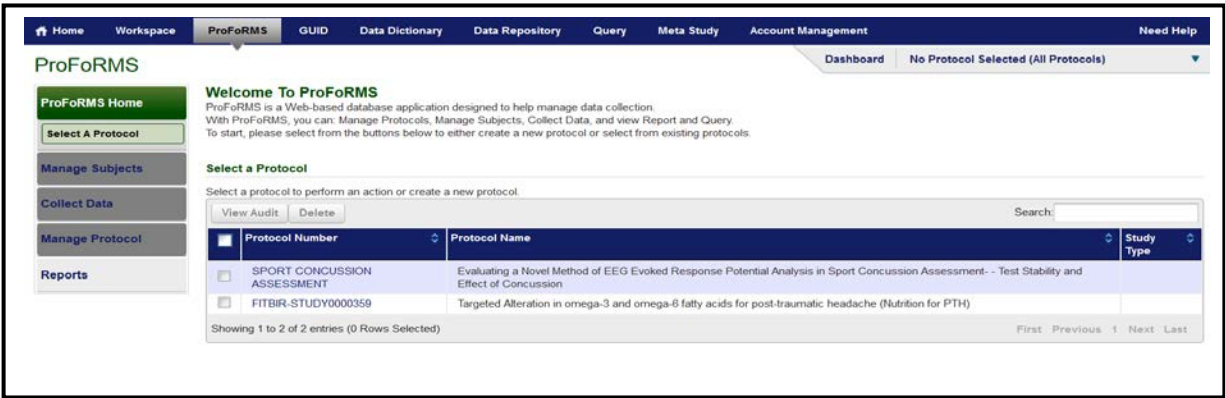
<input type="checkbox"/>	GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
<input checked="" type="checkbox"/>	TBL_INVPO036ZHC	1	Baseline Visit	2018-01-26 15:50	ckm454j4rh3ag5dn
<input type="checkbox"/>	TBL_INVKU074BG6	subjectID	Follow up 36 months	2017-09-09 00:00	
<input type="checkbox"/>	TBL_INVPO036ZHC	1	HIT 6 Mod again	2017-04-05 13:29	
<input type="checkbox"/>	TBL_INVPO036ZHC	1	Follow up 36 months	2017-04-04 05:13	
<input type="checkbox"/>	TBIDEMOD8725JVA	8	Baseline Visit	2017-02-22 15:12	bdhmgU64aolgl
<input type="checkbox"/>	TBL_INVPO036ZHC	1	Baseline Visit	2017-01-26 16:06	adqg6q20cc5qa0v4
<input type="checkbox"/>	TBL_INVPO036ZHC	1	Baseline Visit	2016-10-30 00:00	xkejdndc4hv5af
<input type="checkbox"/>	TBL_INVPO036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7qamriejhv2ahc
<input type="checkbox"/>	TBL_INVPO036ZHC	1	Baseline Visit	2016-04-28 13:20	4y17xd4zumagzmid
<input type="checkbox"/>	TBIDEMOD8725JVA	8	Follow up 36 months	2016-04-28 12:58	6x2birdgwf0uungit
<input type="checkbox"/>	TBL_INVGH486TL7	7	Baseline Visit	2016-04-28 12:57	
<input type="checkbox"/>	TBIDEMOD8725JVA	8	Baseline Visit	2014-06-10 13:45	
<input type="checkbox"/>	TBL_INVGH486TL7	7	Baseline Visit	2014-01-23 09:00	
<input type="checkbox"/>	TBL_INVPO036ZHC	1	Baseline Visit	2013-07-29 14:45	
<input type="checkbox"/>	TBL_INVPO036ZHC	1	Baseline Visit	2013-07-19 08:30	

Showing 1 to 15 of 15 entries (0 Rows Selected) Export options: CSV | Excel
First Previous 1 Next Last

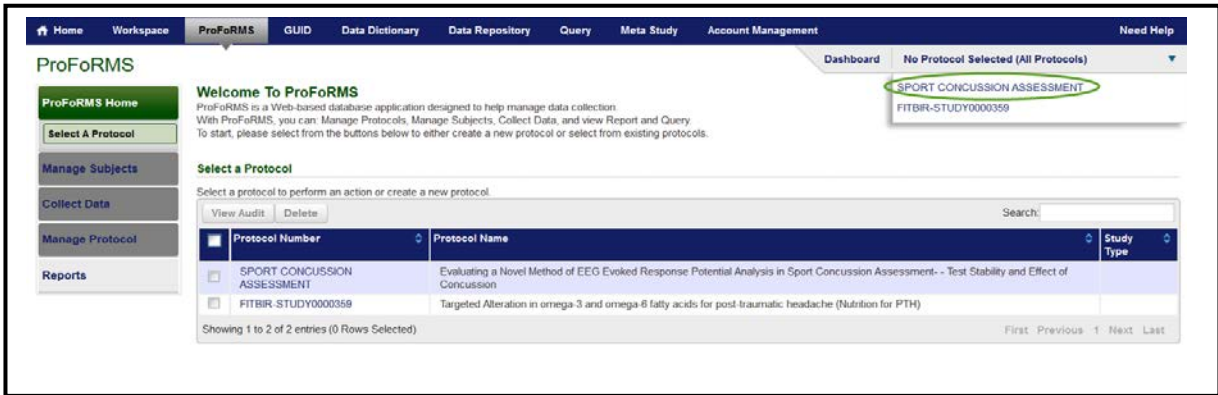
3.6.7 Deleting Scheduled Visits

To Delete Scheduled Visits: Perform the following actions:

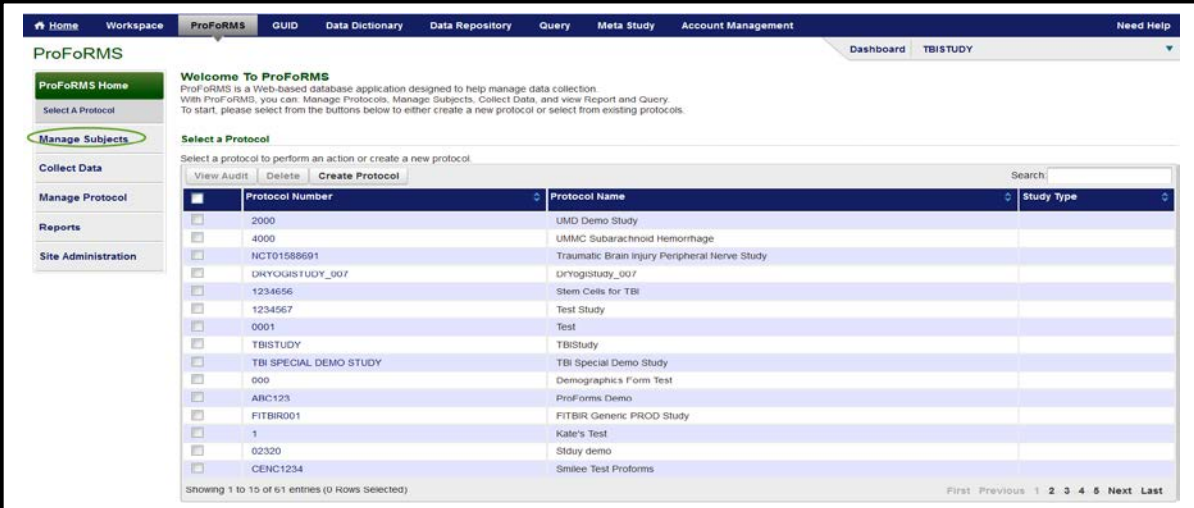
- 1. Click the **ProFoRMS** tab at the top of the screen



- 2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



ProFoRMS

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.


Select a Protocol

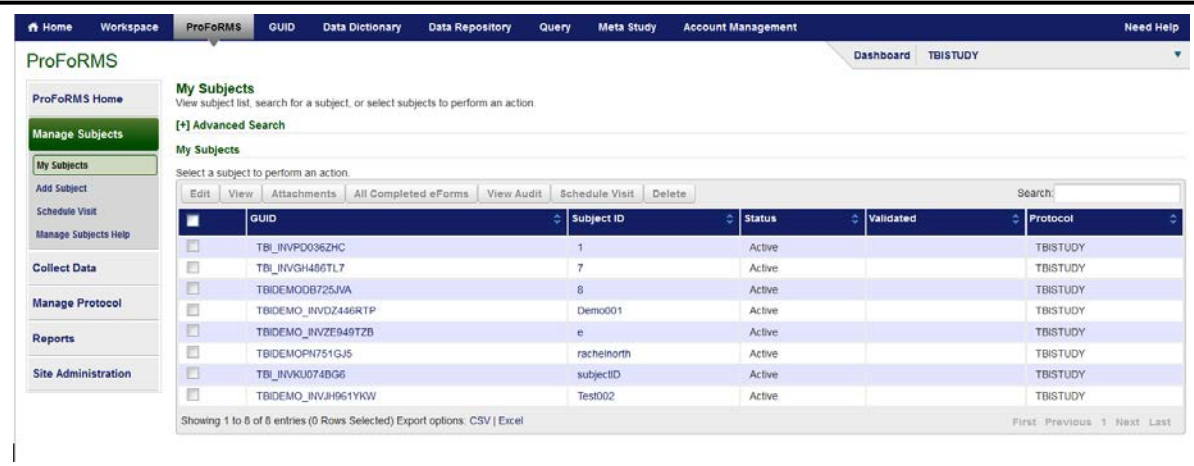
Select a protocol to perform an action or create a new protocol.

View Audit | Delete | Create Protocol

	Protocol Number	Protocol Name	Study Type
<input type="checkbox"/>	2000	UMD Demo Study	
<input type="checkbox"/>	4000	UMMC Subarachnoid Hemorrhage	
<input type="checkbox"/>	NCT01585691	Traumatic Brain Injury Peripheral Nerve Study	
<input type="checkbox"/>	DRYOGISTUDY_007	DRYogistudy_007	
<input type="checkbox"/>	1234656	Stem Cells for TBI	
<input type="checkbox"/>	1234567	Test Study	
<input type="checkbox"/>	0001	Test	
<input type="checkbox"/>	TBISTUDY	TBISTudy	
<input type="checkbox"/>	TBI SPECIAL DEMO STUDY	TBI Special Demo Study	
<input type="checkbox"/>	000	Demographics Form Test	
<input type="checkbox"/>	AIRC123	ProFoRMS Demo	
<input type="checkbox"/>	FITBIR001	FITBIR Generic PROD Study	
<input type="checkbox"/>	1	Kate's Test	
<input type="checkbox"/>	02320	Stiduy demo	
<input type="checkbox"/>	CENC1234	Smilee Test Protforms	

Showing 1 to 15 of 61 entries (0 Rows Selected) First Previous 1 2 3 4 5 Next Last

4. My Subjects page appears with in a list that can be sorted by clicking on the arrows on any field using the  symbol.



ProFoRMS

My Subjects

View subject list, search for a subject, or select subjects to perform an action

[+] Advanced Search

My Subjects

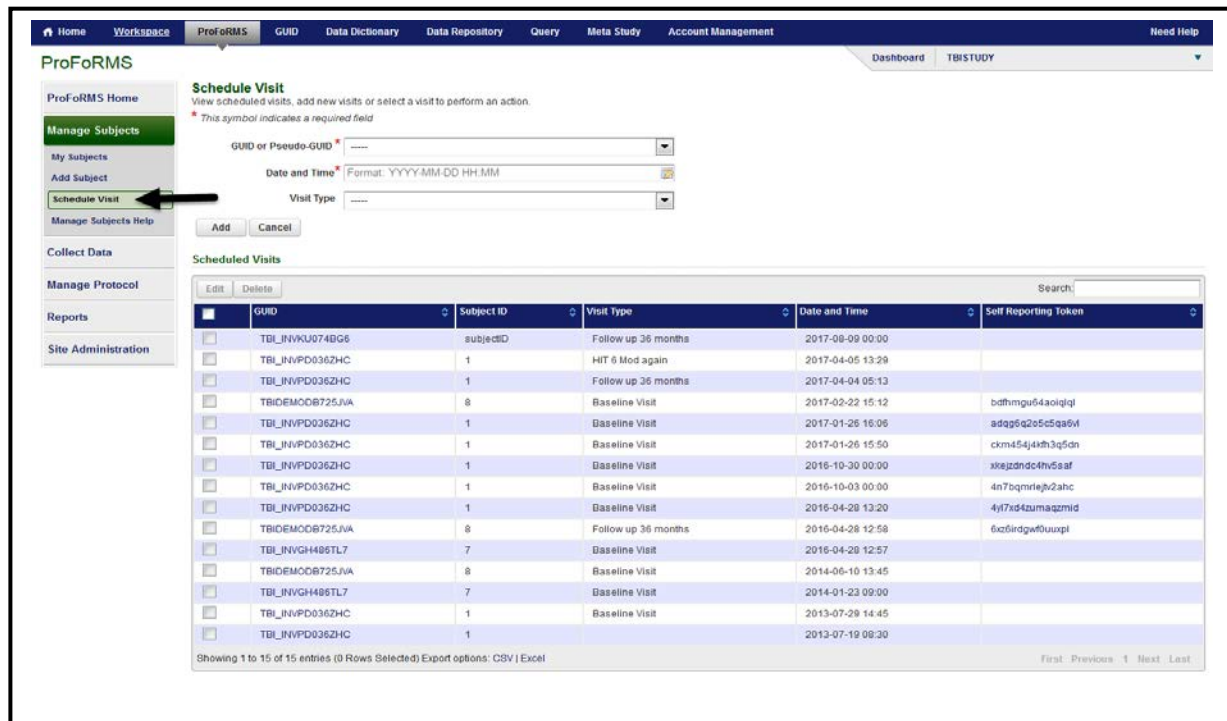
Select a subject to perform an action.

Edit | View | Attachments | All Completed eForms | View Audit | Schedule Visit | Delete

	GUID	Subject ID	Status	Validated	Protocol
<input type="checkbox"/>	TBI_INVPO36ZHC	1	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVGH486TL7	7	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO08725JVA	8	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZ446RTP	Demo001	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZE949TZB	e	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMOPN751GJ5	rachelnorth	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVH061YKW	Test002	Active		TBISTUDY

Showing 1 to 8 of 8 entries (0 Rows Selected) Export options: CSV | Excel First Previous 1 Next Last

5. Click the **Schedule Visit** tab on the left-side tool bar.



ProFoRMS

Schedule Visit
View scheduled visits, add new visits or select a visit to perform an action.
* This symbol indicates a required field

GUID or Pseudo-GUID:

Date and Time: Format: YYYY-MM-DD HH:MM

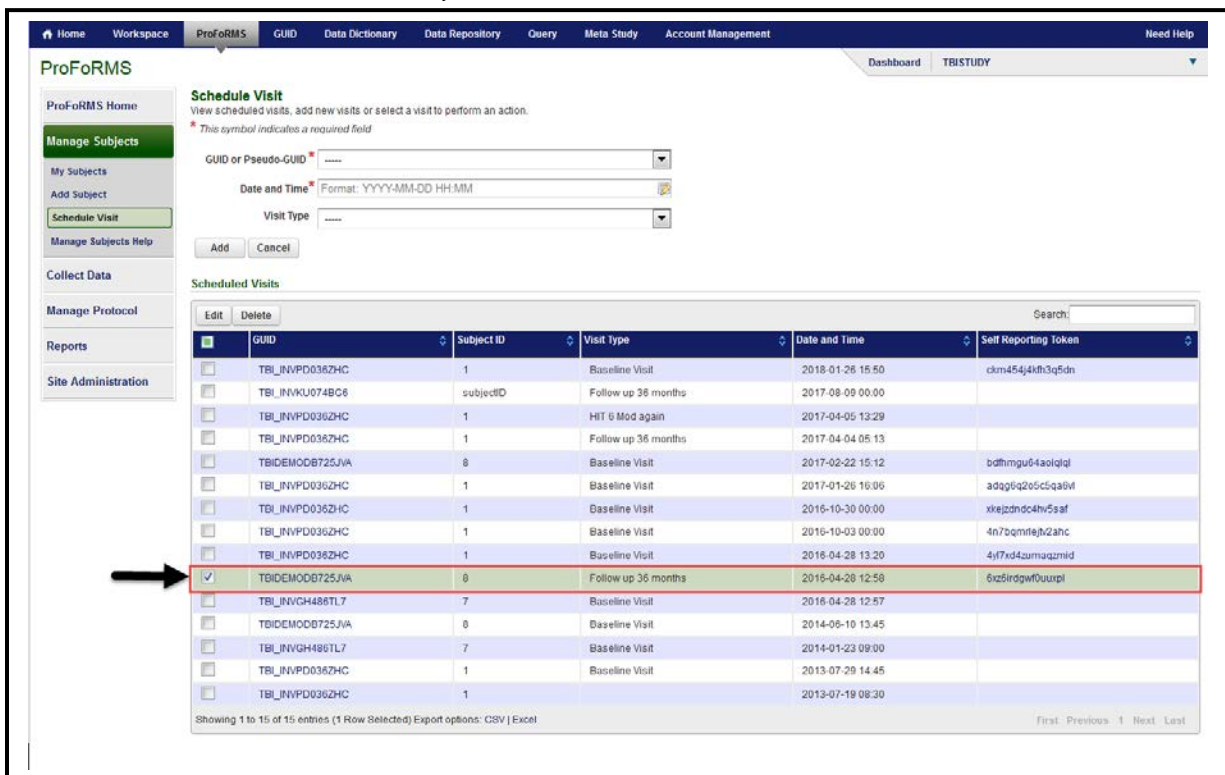
Visit Type:

Scheduled Visits

	GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Follow up 36 months	2017-08-09 00:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	HIT 6 Mod again	2017-04-05 13:29	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Follow up 36 months	2017-04-04 05:13	
<input type="checkbox"/>	TBIDEMOC06725JVA	8	Baseline Visit	2017-02-22 15:12	bdhmgug64oiglg
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 16:06	adqg6q2o5c5a6v
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 15:50	ckm454j4kh3q5dn
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-30 00:00	xkejdndc4hv5af
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqmrfj2znc
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-04-28 13:20	4y17xd4zmagzmid
<input type="checkbox"/>	TBIDEMOC06725JVA	8	Follow up 36 months	2016-04-28 12:58	6xz6rdgwf0uunpl
<input type="checkbox"/>	TBI_INVG4486TL7	7	Baseline Visit	2016-04-28 12:57	
<input type="checkbox"/>	TBIDEMOC06725JVA	8	Baseline Visit	2014-06-10 13:45	
<input type="checkbox"/>	TBI_INVG4486TL7	7	Baseline Visit	2014-01-23 09:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2013-07-29 14:45	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2013-07-19 08:30	

Showing 1 to 15 of 15 entries (0 Rows Selected) Export options: CSV | Excel

6. The **Schedule Visit** page appears from where you can **Delete** a scheduled visit. Select the **Check-box** next to a visit you would like to delete.



ProFoRMS

Schedule Visit
View scheduled visits, add new visits or select a visit to perform an action.
* This symbol indicates a required field

GUID or Pseudo-GUID:

Date and Time: Format: YYYY-MM-DD HH:MM

Visit Type:

Scheduled Visits

	GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2018-01-26 15:50	ckm454j4kh3q5dn
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Follow up 36 months	2017-08-09 00:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	HIT 6 Mod again	2017-04-05 13:29	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Follow up 36 months	2017-04-04 05:13	
<input type="checkbox"/>	TBIDEMOC06725JVA	8	Baseline Visit	2017-02-22 15:12	bdhmgug64oiglg
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 16:06	adqg6q2o5c5a6v
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-30 00:00	xkejdndc4hv5af
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqmrfj2znc
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-04-28 13:20	4y17xd4zmagzmid
<input checked="" type="checkbox"/>	TBIDEMOC06725JVA	8	Follow up 36 months	2016-04-28 12:58	6xz6rdgwf0uunpl
<input type="checkbox"/>	TBI_INVG4486TL7	7	Baseline Visit	2016-04-28 12:57	
<input type="checkbox"/>	TBIDEMOC06725JVA	8	Baseline Visit	2014-06-10 13:45	
<input type="checkbox"/>	TBI_INVG4486TL7	7	Baseline Visit	2014-01-23 09:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2013-07-29 14:45	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2013-07-19 08:30	

Showing 1 to 15 of 15 entries (1 Row Selected) Export options: CSV | Excel

7. Click the **Delete** button.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TRISTUDY

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

Schedule Visit

View scheduled visits, add new visits or select a visit to perform an action.

* This symbol indicates a required field

GUID or Pseudo-GUID*

Date and Time* Format: YYYY-MM-DD HH:MM

Visit Type

Add

Cancel

Scheduled Visits

Edit

Delete

	GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2018-01-26 15:50	ckm454j4th3q5dn
<input type="checkbox"/>	TBI_INVKU074BC6	subjectID	Follow up 36 months	2017-08-09 00:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	HIT 6 Mod again	2017-04-05 13:29	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Follow up 36 months	2017-04-04 05:13	
<input type="checkbox"/>	TBIDEMO08725JVA	8	Baseline Visit	2017-02-22 15:12	bdfhmgus4aoiglj
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 16:06	adgg6q2e5c5qa9vl
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-30 00:00	xiejdndc4hv5saf
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqmtejh2ahc
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-04-28 13:20	4yt7rd4zumagzmid
<input checked="" type="checkbox"/>	TBIDEMO08725JVA	8	Follow up 36 months	2016-04-28 12:58	6xz5irdgw0uuxpl
<input type="checkbox"/>	TBI_INVCH488TL7	7	Baseline Visit	2016-04-28 12:57	
<input type="checkbox"/>	TBIDEMO08725JVA	8	Baseline Visit	2014-06-10 13:45	
<input type="checkbox"/>	TBI_INVGH486TL7	7	Baseline Visit	2014-01-23 09:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2013-07-29 14:45	
<input type="checkbox"/>	TBI_INVPD036ZHC	1		2013-07-19 08:30	

Showing 1 to 15 of 15 entries (1 Row Selected) Export options: CSV | Excel

First Previous 1 Next Last

8. A Pop-up button appears: “*Are you sure you want to delete the scheduled visit(s) from the system?*” Click the **Yes** button. Click the **Yes** button to confirm you would want to delete the scheduled visit(s) from the system. Click the **No** button to cancel the update process.

×

Are you sure you want to delete the scheduled visit(s) from the system?

Yes

No

9. The deleted visit will be displayed on the Scheduled Visits list as shown below:

[Home](#)
[Workspace](#)
[ProFORMS](#)
[GUID](#)
[Data Dictionary](#)
[Data Repository](#)
[Query](#)
[Meta Study](#)
[Account Management](#)
[Need Help](#)

ProFORMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

Dashboard

TBSTUDY

Schedule Visit

The patient visit(s) has been deleted successfully.

View scheduled visits, add new visits or select a visit to perform an action.

* This symbol indicates a required field.

GUID or Pseudo-GUID *

Date and Time * Format: YYYY-MM-DD HH:MM

Visit Type *

Add

Cancel

Scheduled Visits

Edit

Delete

Search:

	GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
<input type="checkbox"/>	TBI_INVPO036ZHC	1	Baseline Visit	2018-01-26 15:50	ckm454j4th3q5dn
<input type="checkbox"/>	TBI_INVKU974BG6	subjectID	Follow up 36 months	2017-08-09 00:00	
<input type="checkbox"/>	TBI_INVPO036ZHC	1	HIT 6 Mod again	2017-04-05 13:29	
<input type="checkbox"/>	TBI_INVPO036ZHC	1	Follow up 36 months	2017-04-04 05:13	
<input type="checkbox"/>	TBIDEMOD6725JVA	8	Baseline Visit	2017-02-22 15:12	bdfhmqv64soiglf
<input type="checkbox"/>	TBI_INVPO036ZHC	1	Baseline Visit	2017-01-26 16:06	adag6q2o5c5qa5vl
<input type="checkbox"/>	TBI_INVPO036ZHC	1	Baseline Visit	2016-10-30 00:00	xxejzndc4hv5aaf
<input type="checkbox"/>	TBI_INVPO036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqmtejh2anc
<input type="checkbox"/>	TBI_INVPO036ZHC	1	Baseline Visit	2016-04-28 13:20	4yl7x04zumaqzmld
<input type="checkbox"/>	TBIDEMOD6725JVA	8	Follow up 36 months	2016-04-28 12:58	6xz6indgw0uuxpl
<input type="checkbox"/>	TBI_INVGH486TL7	7	Baseline Visit	2016-04-28 12:57	
<input type="checkbox"/>	TBIDEMOD6725JVA	8	Baseline Visit	2014-06-10 13:45	
<input type="checkbox"/>	TBI_INVGH486TL7	7	Baseline Visit	2014-01-23 09:00	
<input type="checkbox"/>	TBI_INVPO036ZHC	1	Baseline Visit	2013-07-29 14:45	

Showing 1 to 14 of 14 entries (0 Rows Selected) Export options: CSV | Excel

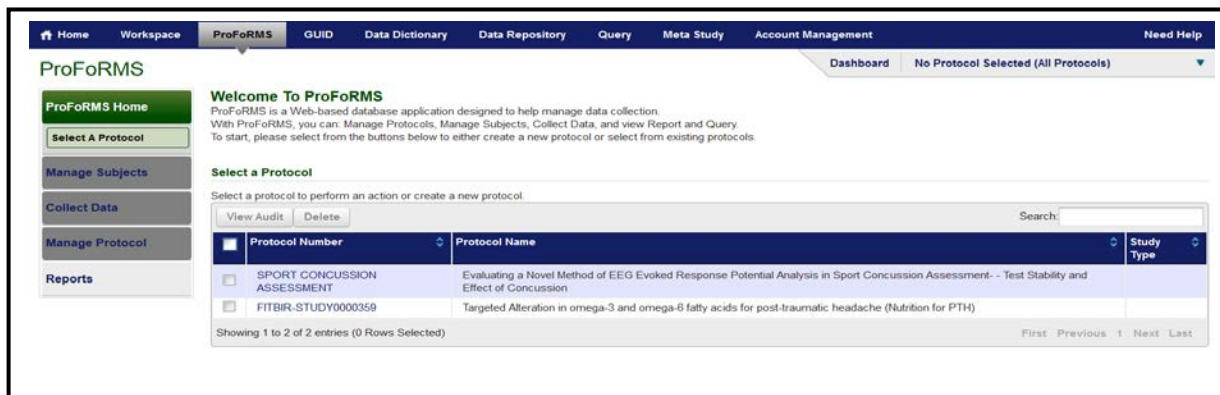
First Previous 1 Next Last

3.6.8 Viewing Scheduled Visits

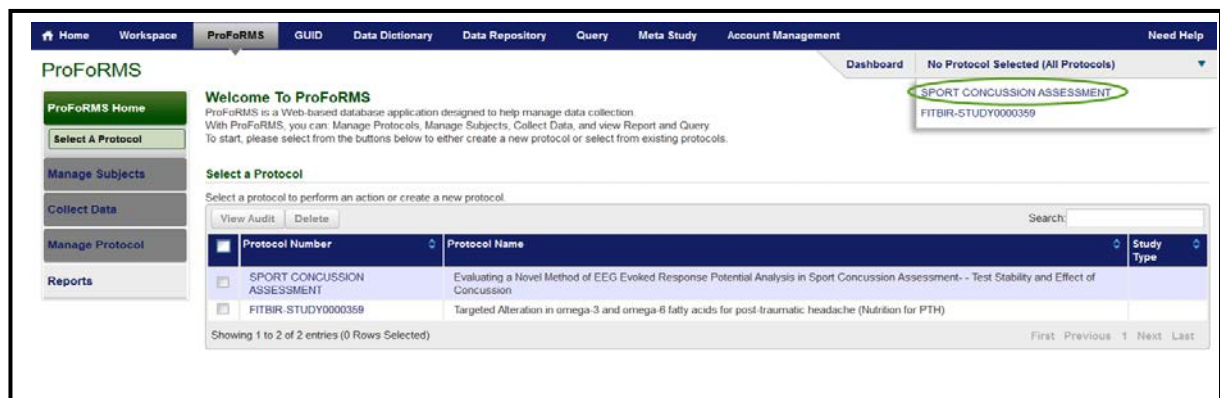
From the **Schedule Visit** page, you can view all your scheduled visits. Sort scheduled visits by **GUID**, **Subject ID**, **Visit Type**, **Date**, and **Time**.

To View All Visits Scheduled on a day: Perform the following actions:

1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand corner.



3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TBISTUDY

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Site Administration

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol.

View Audit

Delete


Create Protocol

Search

	Protocol Number	Protocol Name	Study Type
<input type="checkbox"/>	2000	UMD Demo Study	
<input type="checkbox"/>	4000	UMMC Subarachnoid Hemorrhage	
<input type="checkbox"/>	NCT01586691	Traumatic Brain Injury Peripheral Nerve Study	
<input type="checkbox"/>	DRYOGISTUDY_007	DRYOGISTUDY_007	
<input type="checkbox"/>	1234656	Stem Cells for TBI	
<input type="checkbox"/>	1234567	Test Study	
<input type="checkbox"/>	0001	Test	
<input type="checkbox"/>	TBISTUDY	TBISTudy	
<input type="checkbox"/>	TBI SPECIAL DEMO STUDY	TBI Special Demo Study	
<input type="checkbox"/>	000	Demographics Form Test	
<input type="checkbox"/>	ABC123	ProForms Demo	
<input type="checkbox"/>	FITBIR001	FITBIR Genetic PROD Study	
<input type="checkbox"/>	1	Kate's Test	
<input type="checkbox"/>	02320	Stduy demo	
<input type="checkbox"/>	CENC1234	Smilee Test Protforms	

Showing 1 to 15 of 61 entries (0 Rows Selected)

First Previous 1 2 3 4 5 Next Last

4. My Subjects page appears with in a list that can be sorted by clicking on the arrows on any field using the  symbol.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TBISTUDY

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

My Subjects

View subject list, search for a subject, or select subjects to perform an action

[+] Advanced Search

My Subjects

Select a subject to perform an action.

Edit

View

Attachments

All Completed eForms

View Audit

Schedule Visit

Delete

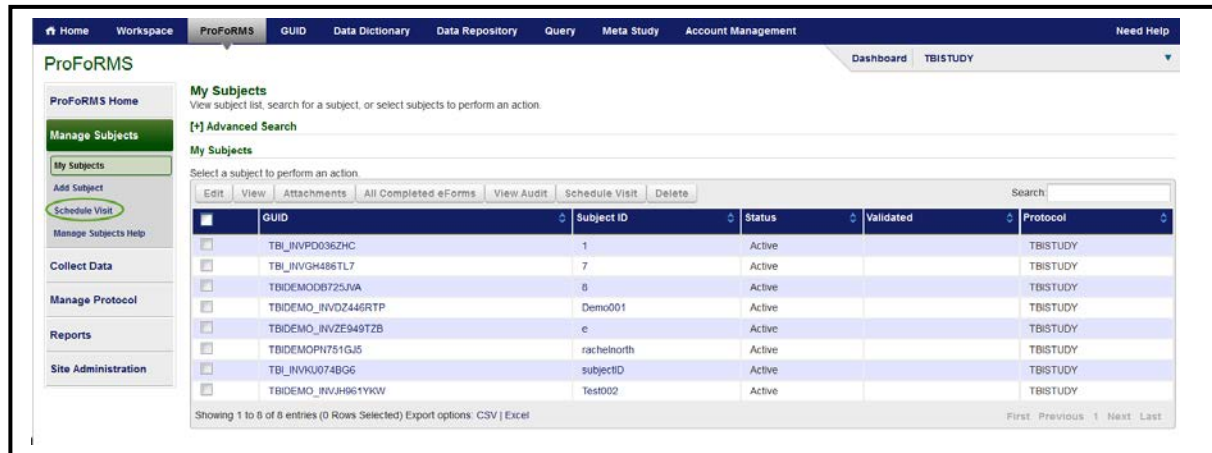
Search

	GUID	Subject ID	Status	Validated	Protocol
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVGH486TL7	7	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO08725JVA	8	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZ446RTP	Demo001	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZE949TZB	e	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMOPN751GJ5	racheimorth	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVJH061YKW	Test002	Active		TBISTUDY

Showing 1 to 6 of 6 entries (0 Rows Selected) Export options: CSV | Excel

First Previous 1 Next Last

5. Click the **Schedule Visit** tab on the left-side tool bar.



ProFORMS

My Subjects
View subject list, search for a subject, or select subjects to perform an action.

[*] Advanced Search

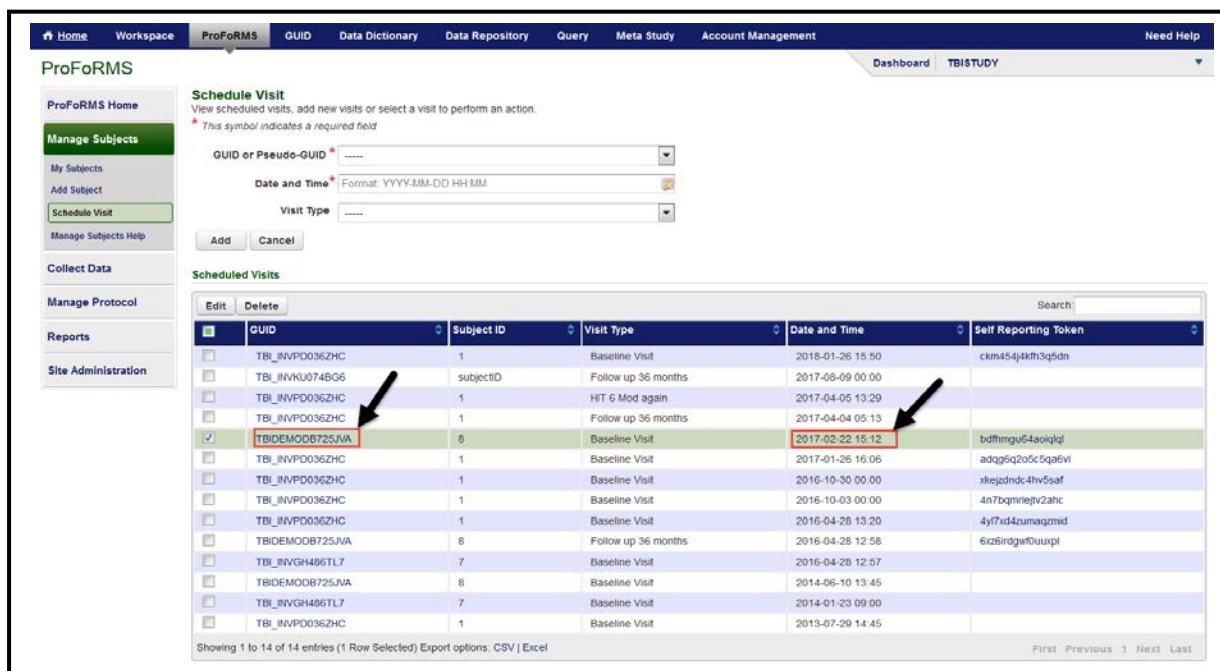
Select a subject to perform an action.

Edit View Attachments All Completed eForms View Audit Schedule Visit Delete Search

	GUID	Subject ID	Status	Validated	Protocol
<input checked="" type="checkbox"/>	TBI_INVPD036ZHC	1	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVG486TL7	7	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMOD8725JVA	8	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVD2446RTP	Demo001	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVZE949TZB	e	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMOPN751GJ5	rachelnorth	Active		TBISTUDY
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Active		TBISTUDY
<input type="checkbox"/>	TBIDEMO_INVJH961YKW	Test002	Active		TBISTUDY

Showing 1 to 8 of 8 entries (0 Rows Selected) Export options: CSV | Excel

6. Click on the **GUID ID** beside the **Day** you wish to view appointments in the Calendar.



ProFORMS

Schedule Visit
View scheduled visits, add new visits or select a visit to perform an action.

* This symbol indicates a required field

GUID or Pseudo-GUID *
Date and Time * Format: YYYY-MM-DD HH:MM
Visit Type *

Add Cancel

Scheduled Visits

Edit Delete Search

	GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
<input checked="" type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2018-01-26 15:50	ckm454j4kth3q5dn
<input type="checkbox"/>	TBI_INVKU074BG6	subjectID	Follow up 36 months	2017-08-09 00:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	HIT 6 Mod again	2017-04-05 13:29	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Follow up 36 months	2017-04-04 05:13	
<input checked="" type="checkbox"/>	TBIDEMOD8725JVA	8	Baseline Visit	2017-02-22 15:12	bdhmgu64a0igkl
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 16:06	adqg6q2o5c5qa6vi
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-30 00:00	xkejzndc4hv5saf
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqnniegjv2ahc
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2016-04-28 13:20	4y7xd4umagzmd
<input type="checkbox"/>	TBIDEMOD8725JVA	8	Follow up 36 months	2016-04-28 12:58	6xz6irdgaf0uuupl
<input type="checkbox"/>	TBI_INVG486TL7	7	Baseline Visit	2016-04-28 12:57	
<input type="checkbox"/>	TBIDEMOD8725JVA	8	Baseline Visit	2014-06-10 13:45	
<input type="checkbox"/>	TBI_INVG486TL7	7	Baseline Visit	2014-01-23 09:00	
<input type="checkbox"/>	TBI_INVPD036ZHC	1	Baseline Visit	2013-07-29 14:45	

Showing 1 to 14 of 14 entries (1 Row Selected) Export options: CSV | Excel

- The View Subject page appears with Subject Information, Protocol Information, Scheduled Visits information, attached documents, and Completed eForms.

[Home](#)
[Workspace](#)
[ProFoRMS](#)
[GUID](#)
[Data Dictionary](#)
[Data Repository](#)
[Query](#)
[Meta Study](#)
[Account Management](#)
[Need Help](#)

ProFoRMS

Dashboard TBI STUDY

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visit

Manage Subjects Help

Collect Data

Manage Protocol

Reports

Site Administration

View Subject:

View subject information or select a section to edit.

[+] Subject Information

[+] Protocol

Associate Subject to Current Protocol ☒

Consent to Future Protocols ☐

Subject Number

Protocol Subject ID 8

Enrollment Date

Subject Site N/A

Completion Date

Status in Current Protocol ☒ Active ☐ Inactive

Edit

[+] Scheduled Visits

Search

Date and Time	Visit Type
2014-06-10 13:45	Baseline Visit
2016-04-28 12:58	Follow up 36 months
2017-02-22 15:12	Baseline Visit

Showing 1 to 3 of 3 entries

First Previous 1 Next Last

Edit

[+] Attachments

[+] Completed eForms

3.7 COLLECT DATA

This feature allows researchers to collect data for subjects and/or specific electronic forms to add new data or modify previously collected data entries, to view and resolve data discrepancies if double entry is specified, perform quality assurance of collected data and monitor subject safety. The module has a functionality that assures that changes are tracked in the system and can be viewed in [Audit Logs](#).

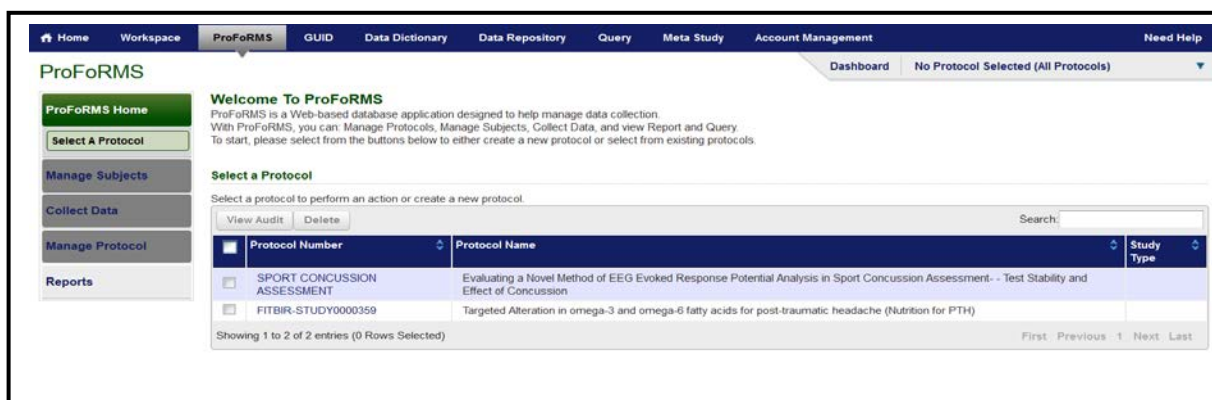
Clinical data may be captured electronically at its source, or in paper form and later transcribed into the system. There are two options for collecting data in ProFORMS:

1. Real-time data entry method; and
2. Pen and paper method, which is then transcribed into ProFoRMS at a later date.

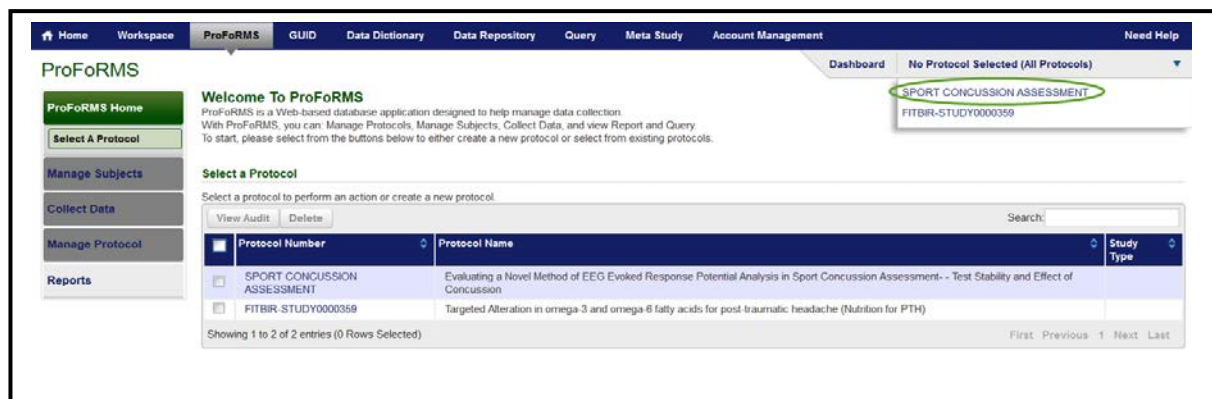
3.7.1 Data Collection (by Subject)

To start Data Collection: Perform the following actions:

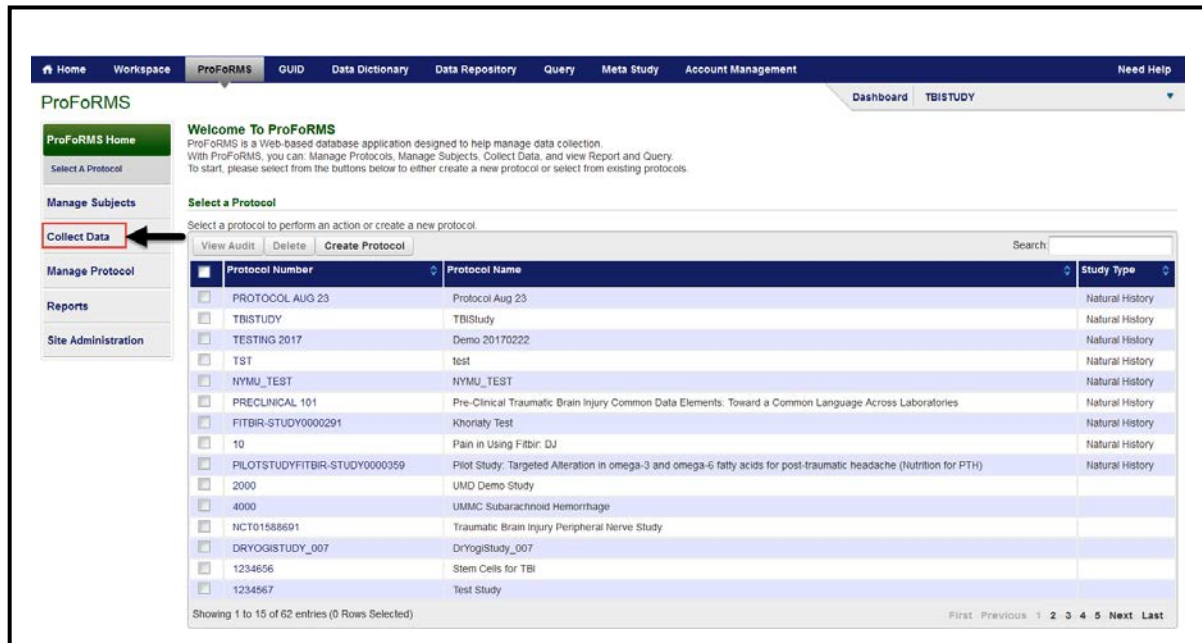
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



Welcome To ProFoRMS
ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

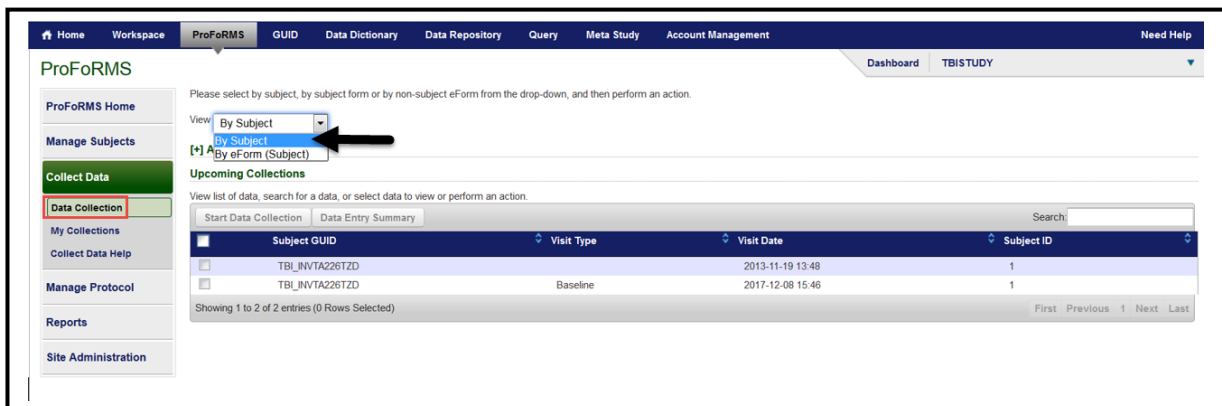
Select a Protocol
Select a protocol to perform an action or create a new protocol.

View Audit Delete Create Protocol

Protocol Number	Protocol Name	Study Type
PROTOCOL AUG 23	Protocol Aug 23	Natural History
TBIStudy	TBIStudy	Natural History
TESTING 2017	Demo 20170222	Natural History
TST	test	Natural History
NYMU_TEST	NYMU_TEST	Natural History
PRECLINICAL 101	Pre-Clinical Traumatic Brain Injury Common Data Elements: Toward a Common Language Across Laboratories	Natural History
FITBIR-STUDY0000291	Khonaty Test	Natural History
10	Pain in Using Fitbir: DJ	Natural History
PILOTSTUDYFITBIR-STUDY0000359	Pilot Study: Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Natural History
2000	UMD Demo Study	
4000	UMMC Subarachnoid Hemorrhage	
NCT01588691	Traumatic Brain Injury Peripheral Nerve Study	
DRYOGISTUDY_007	Dryogistudy_007	
1234565	Stem Cells for TBI	
1234567	Test Study	

Showing 1 to 15 of 62 entries (0 Rows Selected)

4. Click the **Collect Data** on the left-side tool bar. Select by subject, by subject form or by non-subject eForm from the drop-down, and select the desired option: View – (By Subject or By eForm (Subject)). The Data Collection eForms page opens with the list of **Upcoming Collections** when **View** by **Subject** is selected. Depending on the view you selected, the table will display either the list of subjects, or the list of forms.



Please select by subject, by subject form or by non-subject eForm from the drop-down, and then perform an action.

View: By Subject (selected)

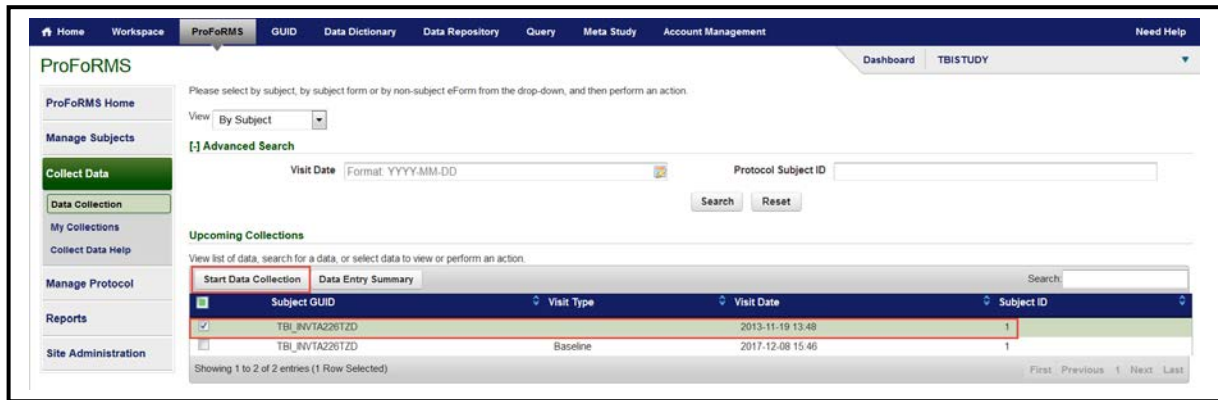
Upcoming Collections
View list of data, search for a data, or select data to view or perform an action.

Start Data Collection Data Entry Summary

Subject GUID	Visit Type	Visit Date	Subject ID
TBI_INVT226T2D	Baseline	2013-11-19 13:48	1
TBI_INVT226T2D		2017-12-08 15:46	1

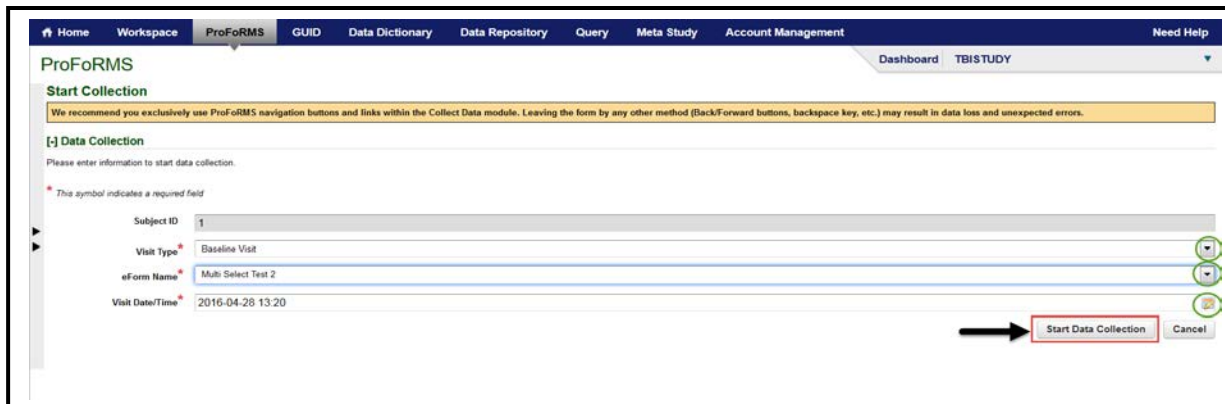
Showing 1 to 2 of 2 entries (0 Rows Selected)

- To start data collection, **Select the Check-box beside the Subject GUID**, and Press the **Start Data Collection** button. **Note:** We recommend you exclusively use ProFoRMS navigation buttons and links within the Collect Data module. Leaving the form by any other method (Back/Forward buttons, backspace key, etc.) may result in data loss and unexpected errors.



Subject GUID	Visit Type	Visit Date	Subject ID
<input checked="" type="checkbox"/> TBI_INV1A26TZD		2013-11-19 13:48	1
<input type="checkbox"/> TBI_INV1A26TZD	Baseline	2017-12-08 15:46	1

- Enter the required information (Subject ID, Visit Type, eForm Name, Visit Date/Time) and Click the **Start Data Collection** button. **NOTE:** Visit Type and Visit Data/Time is auto-populated, but can be edited.



Start Collection

We recommend you exclusively use ProFoRMS navigation buttons and links within the Collect Data module. Leaving the form by any other method (Back/Forward buttons, backspace key, etc.) may result in data loss and unexpected errors.

[+] Data Collection

Please enter information to start data collection.

* This symbol indicates a required field

Subject ID: 1

Visit Type: Baseline Visit

eForm Name: Multi Select Test 2

Visit Date/Time: 2016-04-28 13:20

Start Data Collection Cancel

- Enter the subject information, and Protocol information and other fields to add a subject. Mandatory fields are marked with asterisk *. Click the **Save** button. **Note:** Visit Type and Visit Date/Time is auto-populated, but it can be edited. Click the **Save** button. Once an eform has been saved, you will be directed to My Collections page which provides a table of the eforms and their statuses.

NOTE: There are certain fields that are auto-populated on the form beyond Visit Type and Visit Date/Time. This can be configured when creating/editing a visit type under the Protocol Information. Mandatory fields do not have to be completed to save a collection. The save button will save the user's progress automatically regardless of its current completion status.

Home
Workspace
ProFoRMS
GUID
Data Dictionary
Data Repository
Query
Meta Study
Account Management
Need Help

Dashboard
TBISTUDY

Start Collection

[+] Data Collection

Please enter information to start data collection.

* This symbol indicates a required field

Subject ID
7

Visit Type
Baseline Visit

eForm Name
Glasgow Coma Scale

Visit Date/Time
2016-04-28 12:57

eForms For This Visit Type

☒ Multi Select Test 2
☒ Glasgow Coma Scale
☐ June24th2016
☐ Build8640
☐ QV form

Glasgow Coma Scale

Glasgow Coma Scale or Pediatric Glasgow Coma Scale

Scale used:

☒ Glasgow Coma Scale (GCS)
☐ Pediatric Glasgow Coma Scale (PGCS)

Best eye response * (choose one):

☐ 1
☒ 2
☐ 3
☐ 4

GCS codes: 1= No eye opening; 2= Eye opening to pain; 3= Eye opening to verbal command; 4= Eyes open spontaneously PGCS codes: 1= No eye opening; 2= Eye opening to pain; 3= Eye opening to speech; 4= Eyes open spontaneously

Motor response * (choose one):

☐ 1
☒ 2
☐ 3
☐ 4
☐ 5
☐ 6

GCS codes: 1= No motor response; 2= Abnormal extension; 3= Abnormal flexion; 4= Flexion withdrawal; 5= Localizes pain; 6= Obeys command PGCS codes: 1= No motor response; 2= Extension to pain; 3= Flexion to pain; 4= Withdrawal from pain; 5= Localizing pain; 6= Obeys commands

Verbal response * (choose one):

☐ 1
☐ 3
☒ 4
☐ 5

GCS codes: 1= No verbal response; 2= Incomprehensible sound; 3= Inappropriate words; 4= Confused; 5= Oriented PGCS codes: 1= No vocal response; 2= Inconsolable, agitated; 3= Inconsistently consolable, moaning; 4= Cries, but is consolable, inappropriate interactions; 5= Smiles, oriented to sounds, follows objects, interacts

Total score*: 8

(3-15: calculated field)

GCS confounders type (choose all that apply):

☐ GCS Accurate
☒ Alcohol/drugs of abuse
☐ C-spine injury
☐ Hypoxia/hypotension
☐ Hypothermia
☐ Sedation
☐ Paralytic
☐ Unknown

Left pupil measurement

mm (1-9)

Left pupil measurement

☐ Untestable
☐ Unknown

Right pupil measurement

mm (1-9)

Right pupil measurement

☒ Untestable
☐ Unknown

Left pupil shape

☐ Round
☒ Oval
☐ Unknown

Right pupil shape

☐ Round
☒ Oval
☐ Unknown

Left pupil reactivity

☐ Brisk
☒ Sluggish
☐ Nonreactive
☐ Untestable
☐ Unknown

Right pupil reactivity

☐ Brisk
☒ Sluggish
☐ Nonreactive
☐ Untestable
☐ Unknown

☐ Mark As Completed and Enable Locking for Submission

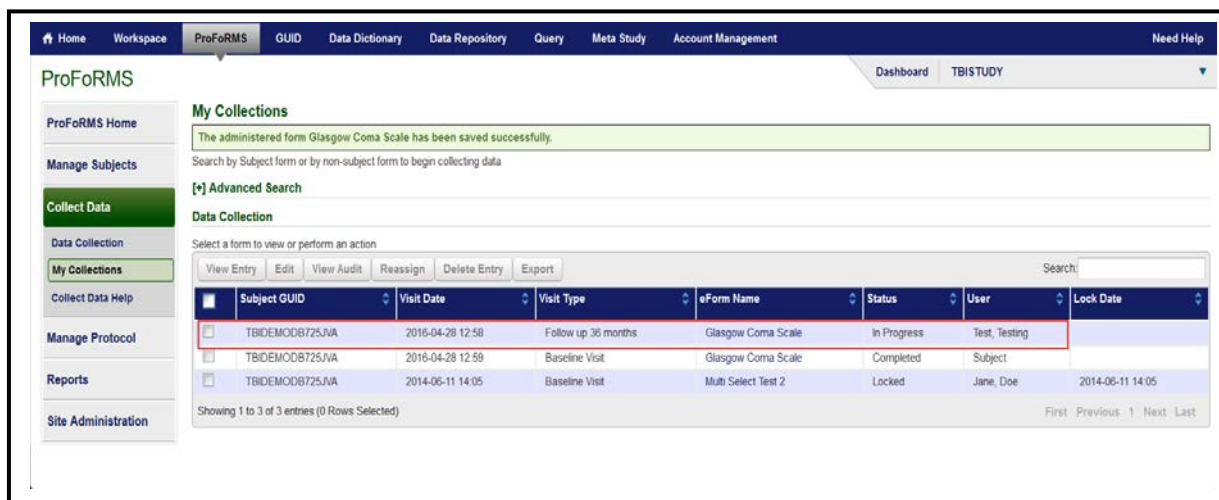
Use the "Previous eForm" button to move to the previous form

Use the "Next eForm" button to move to the next form

<<Previous eForm
Next eForm>>

Save
Save & Exit
Save & Lock
Cancel

8. A visit will be considered “Complete” when all required forms for a particular visit type are labeled “In Progress”. The collection data is saved in **My Collections** page with a confirmation of the changes as shown below:



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

My Collections

The administered form Glasgow Coma Scale has been saved successfully.

Search by Subject form or by non-subject form to begin collecting data

[+] Advanced Search

Data Collection

Select a form to view or perform an action

View Entry Edit View Audit Reassign Delete Entry Export Search

	Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
<input checked="" type="checkbox"/>	TBIDEMO08725.JVA	2016-04-28 12:58	Follow up 36 months	Glasgow Coma Scale	In Progress	Test, Testing	
<input type="checkbox"/>	TBIDEMO08725.JVA	2016-04-28 12:59	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
<input type="checkbox"/>	TBIDEMO08725.JVA	2014-06-11 14:05	Baseline Visit	Multi Select Test 2	Locked	Jane, Doe	2014-06-11 14:05

Showing 1 to 3 of 3 entries (0 Rows Selected)

First Previous 1 Next Last










ICON KEY

 Notes

 Important

Information

Things to Note:

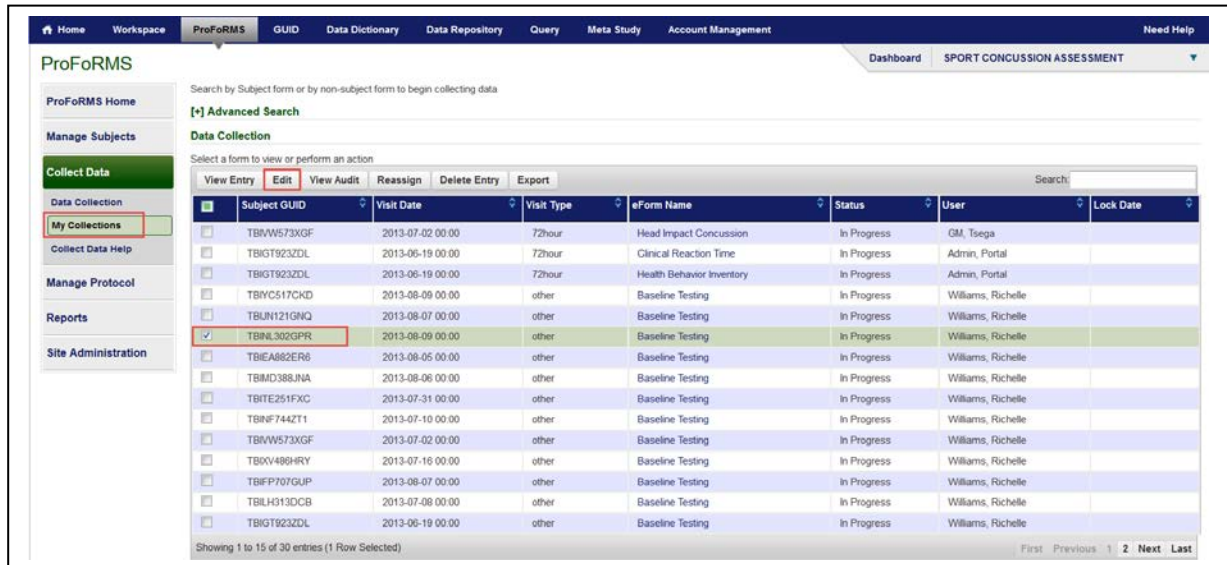
-  To reset the questions on the eform, double-click on the **Radio** buttons
-  To save the eform, use the **Save** button at the bottom of the eform
-  To cancel the data collection process, simply click on the **Cancel** button
-  The system auto-saves the eform every **8 minutes**
-  All Required fields are marked by **red asterisks**
-  Certain questions are greyed-out by **Skip logic**
-  Auto-calculated fields that appear in several forms. Answers will appear if you click on them, but it is **NOT** necessary to save the eform.
-  Green sections are collapsible. User can expand/hide to read further instructions or view scoring sections.
-  To leave the form and complete it at a later date and time, use the **"Save & Exit"** button

3.7.2 Locking the eForm

After entering data in the form and click the Save button, you will be taken to the My Collections view. Forms will continue to show as “In Progress” until they are locked. Data should not be locked untill reviewed and ready for final submission.

To lock your form: Perform the following actions:

1. When the data has been reviewed and is ready to be locked; select the GUID and form you wish to lock from the “My Collections” page to the **ProFoRMS** module



The screenshot shows the ProFoRMS interface with the 'My Collections' view selected in the left sidebar. The main area displays a table of data collection entries. The 'Edit' button in the top toolbar is highlighted with a red box. The entry with GUID TBNL302GPR is selected, indicated by a green background and a checkmark in the first column.

	Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
<input type="checkbox"/>	TBRVWS73XGF	2013-07-02 00:00	72hour	Head Impact Concussion	In Progress	GM, Tsega	
<input type="checkbox"/>	TBGT923ZDL	2013-06-19 00:00	72hour	Clinical Reaction Time	In Progress	Admin, Portal	
<input type="checkbox"/>	TBGT923ZDL	2013-06-19 00:00	72hour	Health Behavior Inventory	In Progress	Admin, Portal	
<input type="checkbox"/>	TBVC517CKD	2013-08-09 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBLN121GNQ	2013-08-07 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input checked="" type="checkbox"/>	TBNL302GPR	2013-08-09 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBIEA882ER6	2013-08-05 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBMD388JNA	2013-08-06 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBITE251FXC	2013-07-31 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBNF744ZT1	2013-07-10 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBRVWS73XGF	2013-07-02 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBKV4894RY	2013-07-16 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBFP707GUP	2013-08-07 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBLH313DCB	2013-07-08 00:00	other	Baseline Testing	In Progress	Williams, Richelle	
<input type="checkbox"/>	TBGT923ZDL	2013-06-19 00:00	other	Baseline Testing	In Progress	Williams, Richelle	

Showing 1 to 15 of 30 entries (1 Row Selected)

- Once all of the required questions have been completed, click on the checkbox, “**Mark as Complete and Enable Lock**”. If the e-signature is enabled in the protocol information section, then a pop-up will display asking for the user's electronic signature by inputting their password.

Home
Workspace
ProFoRMS
GUID
Data Dictionary
Data Repository
Query
Meta Study
Account Management
Need Help

Dashboard
TBISTUDY

ProFoRMS
Start Collection
[] Data Collection
Please enter information to start data collection.
* This symbol indicates a required field

Subject ID: 7
Visit Type: Baseline Visit
eForm Name: Glasgow Coma Scale
Visit Date/Time: 2016-04-28 12:57

eForms For This Visit Type
☒ Multi Select Test 2
☒ **Glasgow Coma Scale**
☐ June24th2016
☐ Build0640
☐ OV form

Glasgow Coma Scale
Glasgow Coma Scale or Pediatric Glasgow Coma Scale
Glasgow Coma Scale or Pediatric Glasgow Coma Scale
Scale used:
☒ Glasgow Coma Scale (GCS)
☐ Pediatric Glasgow Coma Scale (PGCS)
Best eye response * (choose one):
☐ 1
☒ 2
☐ 3
☐ 4
GCS codes: 1= No eye opening; 2= Eye opening to pain; 3= Eye opening to verbal command; 4= Eyes open spontaneously PGCS codes: 1= No eye opening; 2= Eye opening to pain; 3= Eye opening to speech; 4= Eyes open spontaneously
Motor response * (choose one):
☐ 1
☒ 2
☐ 3
☐ 4
☐ 5
☐ 6
GCS codes: 1= No motor response; 2= Abnormal extension; 3= Abnormal flexion; 4= Flexion withdrawal; 5= Localizes pain; 6= Obeys command PGCS codes: 1= No motor response; 2= Extension to pain; 3= Flexion to pain; 4= Withdrawal from pain; 5= Localizing pain; 6= Obeys commands
Verbal response * (choose one):
☐ 1
☐ 3
☒ 4
☐ 5
☐ 2
☐ 5
GCS codes: 1= No verbal response; 2= Incomprehensible sound; 3= Inappropriate words; 4= Confused; 5= Oriented; PGCS codes: 1= No vocal response; 2= Inconsolable, agitated; 3= Inconsistently consolable, moaning; 4= Cries, but is consolable, inappropriate interactions; 5= Smiles, oriented to sounds, follows objects, interacts
Total score*:
3-15; calculated field
8
GCS confounders type (choose all that apply):
☐ GCS Accurate
☒ Alcohol/drugs of abuse
☐ C-spine injury
☐ Hypoxia/hypotension
☐ Hypothermia
☐ Sedation
☐ Paralytic
☐ Unknown
Left pupil measurement
mm (1-9)
3
Left pupil measurement
mm (1-9)
Unstable
Unknown
Right pupil measurement
mm (1-9)
4
Right pupil measurement
mm (1-9)
Unstable
Unknown
Left pupil shape
☐ Round
☒ Oval
☐ Unknown
Right pupil shape
☐ Round
☒ Oval
☐ Unknown
☐ Always or cannot do at all
Total Scores
Mobility:
Activities of daily living (ADL):
Emotional well being:
Stigma:
Social support:
Cognitive impairment:
Communication:
Bodily discomfort:

☐ Mark As Completed and Enable Lock

Save Save & Exit Lock Cancel

- Once a form as been marked as completed, three things will happen: (1) The "Save & Lock" button will be enabled; (2) The system validation will run (3) An audit trial will start if a user changes their response to an answer. If the form failed you will be notified with a list of the errors and why, along with a link to the question that failed the validation. Once all the errors have been resolved, the user will be able to "save & lock" the form.

Home
Workspace
ProFoRMS
GUID
Data Dictionary
Data Repository
Query
Meta Study
Account Management
Need Help

Dashboard
TBISTUDY

ProFoRMS

Start Collection

[+] Data Collection

Please enter information to start data collection.

* This symbol indicates a required field

Subject ID: 7

Visit Type: Baseline Visit

eForm Name: Glasgow Coma Scale

Visit DateTime: 2016-04-28 12:57

☒ Locked
☐ In Progress
☐ Completed
☐ Not Started*

Letter R inside circle means required form for that visit type

eForms For This Visit Type

- ☒ Multi Select Test 2
- ☒ Glasgow Coma Scale
- ☐ June24th2016
- ☐ Bulk8540
- ☐ QY form

Glasgow Coma Scale

Glasgow Coma Scale or Pediatric Glasgow Coma Scale

Glasgow Coma Scale or Pediatric Glasgow Coma Scale

Scale used:

☒ Glasgow Coma Scale (GCS)
☐ Pediatric Glasgow Coma Scale (PGCS)

Best eye response * (choose one):

☐ 1
☒ 2
☐ 3
☐ 4

GCS codes: 1= No eye opening, 2= Eye opening to pain, 3= Eye opening to verbal command, 4= Eyes open spontaneously PGCS codes: 1= No eye opening, 2= Eye opening to pain, 3= Eye opening to speech, 4= Eyes open spontaneously

Motor response * (choose one):

☐ 1
☒ 2
☐ 3
☐ 4
☐ 5
☐ 6

GCS codes: 1= No motor response, 2= Abnormal extension, 3= Abnormal flexion, 4= Flexion withdrawal, 5= Localizes pain, 6= Obeys command PGCS codes: 1= No motor response, 2= Extension to pain, 3= Flexion to pain, 4= Withdrawal from pain, 5= Localizing pain, 6= Obeys commands

Verbal response * (choose one):

☐ 1
☐ 3
☒ 4
☐ 2
☐ 5

GCS codes: 1= No verbal response, 2= Incomprehensible sound, 3= Inappropriate words, 4= Confused, 5= Oriented, PGCS codes: 1= No vocal response, 2= Inconsolable, agitated, 3= Inconsistently consolable, moaning, 4= Cries, but is consolable, inappropriate interactions, 5= Smiles, oriented to sounds, follows objects, interacts

Total score*:

8

(3-16; calculated field)

GCS confounders type (choose all that apply):

☐ GCS Accurate
☒ Alcohol/drugs of abuse
☐ C-spine injury
☐ Hypoxia/hypotension
☐ Hypothermia
☐ Sedation
☐ Paralytic
☐ Unknown

Left pupil measurement

mm (1.9):

Left pupil measurement

☐ Untestable
☒ Unknown

Right pupil measurement

mm (1.9):

Right pupil measurement

☒ Untestable
☐ Unknown

Left pupil shape

☐ Round
☒ Oval
☐ Unknown

Right pupil shape

☐ Round
☒ Oval
☐ Unknown

Full sibling
Half sibling

X) Additional Conditions

Other condition, please specify

Family history?

☐ Yes
☒ No
☐ Unknown

Relationship of family member to subject? (check all that apply)

☐ Mother
☐ Father
☐ Child
☐ Full sibling
☐ Half sibling

Repeat

☒ Mark As Completed and Enable Lock

4. Once the form is locked, a “**Collection Data Lock Confirmation**” pop-up window will appear to validate if all information is complete. Select the check-box and Click the **Lock & Exit** button.



Collect Data Lock Confirmation

Study Name: Parkinson's Disease
Form Name: Family History
Subject GUID: PDXN792ZLQ
Visit Date: 2014-09-18 21:02
Visit Type : Baseline
Data Entered By : testadmin

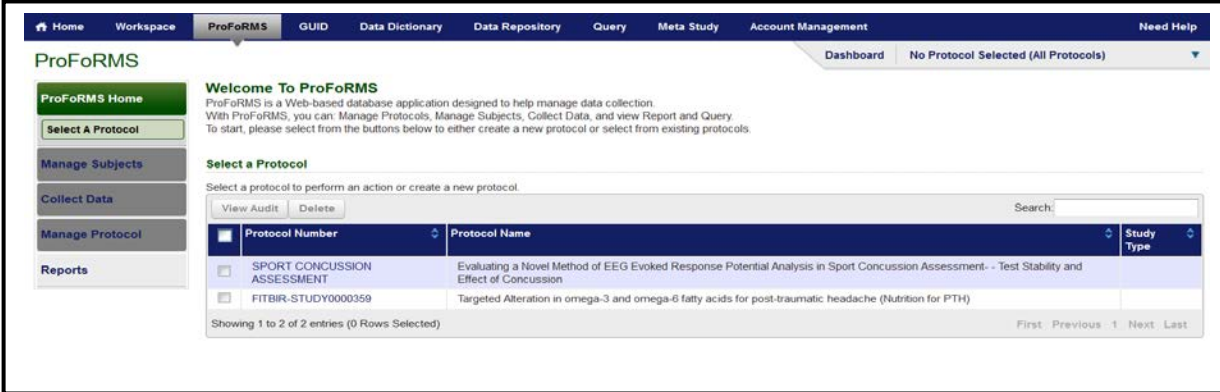
☐ I hereby confirm that all data entry for this form is accurate and complete to the best of my knowledge.

[View Completed Form](#) [Lock & Exit](#) [Cancel](#)

3.7.3 Viewing Data Collection eForms

To view **Data Collection eForms**: Perform the following actions:

1. Navigate to the **ProFoRMS** module



Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

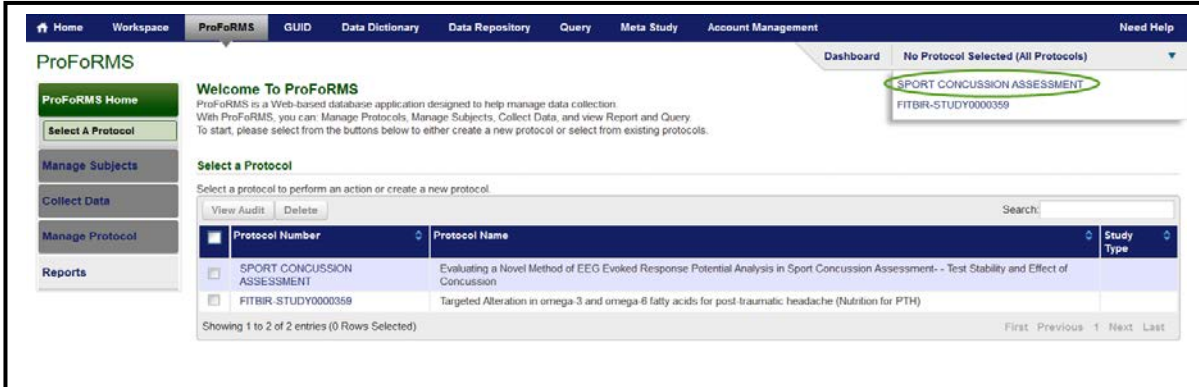
Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

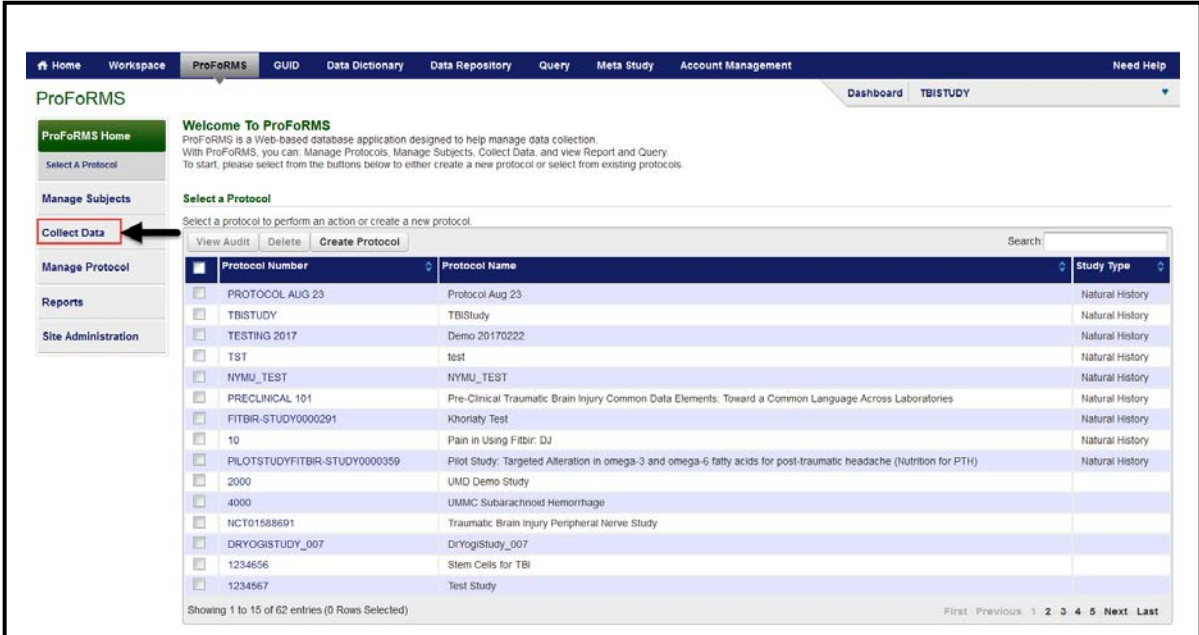
Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

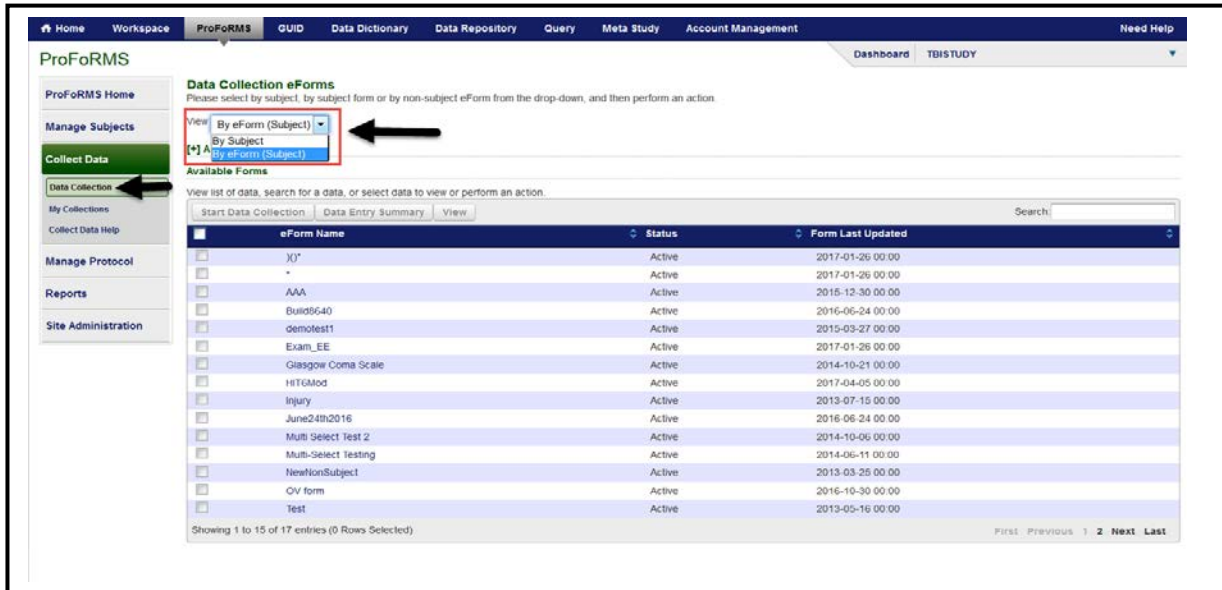
Select a protocol to perform an action or create a new protocol.

View Audit Delete Create Protocol Search:

Protocol Number	Protocol Name	Study Type
PROTOCOL AUG 23	Protocol Aug 23	Natural History
TBI STUDY	TBI Study	Natural History
TESTING 2017	Demo 20170222	Natural History
TST	test	Natural History
NYMU_TEST	NYMU_TEST	Natural History
PRECLINICAL 101	Pre-Clinical Traumatic Brain Injury Common Data Elements: Toward a Common Language Across Laboratories	Natural History
FITBIR-STUDY0000291	Khoraly Test	Natural History
10	Pain in Using Fitbir: DJ	Natural History
PILOTSTUDYFITBIR-STUDY0000359	Pilot Study: Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Natural History
2000	UMD Demo Study	
4000	UMMC Subarachnoid Hemorrhage	
NCT01585691	Traumatic Brain Injury Peripheral Nerve Study	
DRYOGISTUDY_007	DRYogistudy_007	
1234656	Stem Cells for TBI	
1234567	Test Study	

Showing 1 to 15 of 62 entries (0 Rows Selected) First Previous 1 2 3 4 5 Next Last

- Click the **Data Collect** on the left-side tool bar. Select by subject, by subject form or by non-subject eForm from the drop-down, and select the desired option: View – (By Subject or By eForm (Subject)). The Data Collection eForms page opens with the list of **Upcoming Collections** when **View by Subject** is selected. Depending on the view you selected, the table will display either the list of subjects, or the list of forms.



ProFoRMS

Data Collection eForms
Please select by subject, by subject form or by non-subject eForm from the drop-down, and then perform an action.

View: **By eForm (Subject)** | By Subject | By eForm (Subject)

Available Forms
View list of data, search for a data, or select data to view or perform an action.

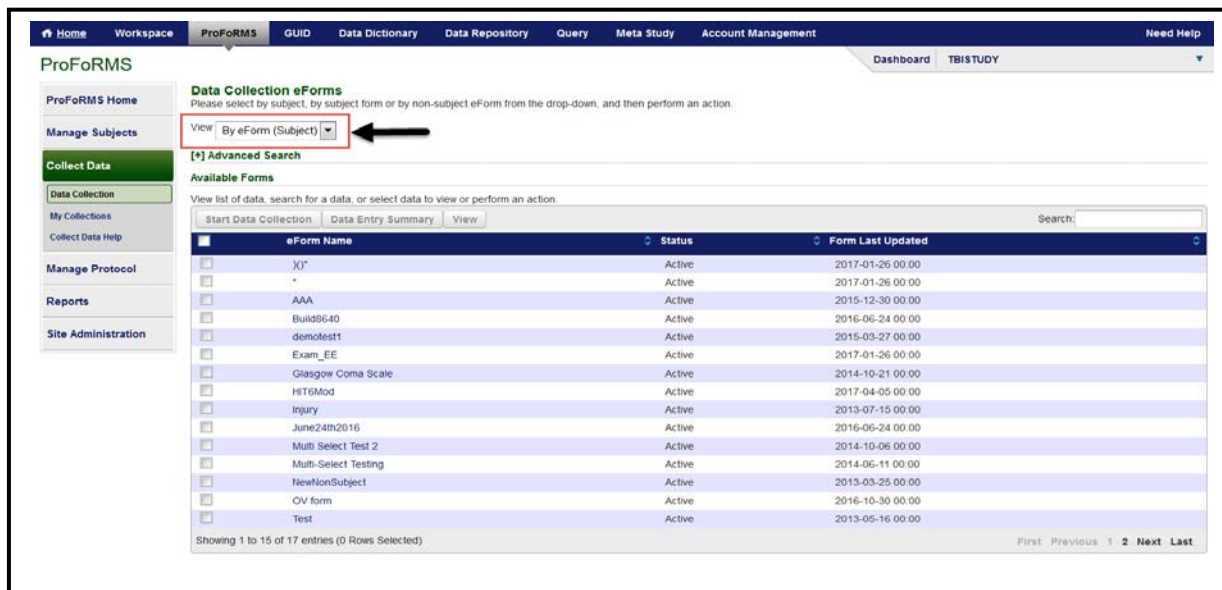
Start Data Collection | Data Entry Summary | View

eForm Name	Status	Form Last Updated
X0*	Active	2017-01-26 00:00
-	Active	2017-01-26 00:00
AAA	Active	2015-12-30 00:00
Build9640	Active	2016-06-24 00:00
demotest1	Active	2015-03-27 00:00
Exam_EE	Active	2017-01-26 00:00
Glasgow Coma Scale	Active	2014-10-21 00:00
HIT6Mod	Active	2017-04-05 00:00
Injury	Active	2013-07-15 00:00
June24th2016	Active	2016-06-24 00:00
Multi Select Test 2	Active	2014-10-06 00:00
Multi-Select Testing	Active	2014-06-11 00:00
NewNonSubject	Active	2013-03-25 00:00
OV form	Active	2016-10-30 00:00
Test	Active	2013-05-16 00:00

Showing 1 to 15 of 17 entries (0 Rows Selected)

First Previous 1 2 Next Last

- The Data Collection eForms page opens with the list of **Available Forms** when **View by eForm (Subject)** is selected.



ProFoRMS

Data Collection eForms
Please select by subject, by subject form or by non-subject eForm from the drop-down, and then perform an action.

View: **By eForm (Subject)** | By Subject | By eForm (Subject)

Available Forms
View list of data, search for a data, or select data to view or perform an action.

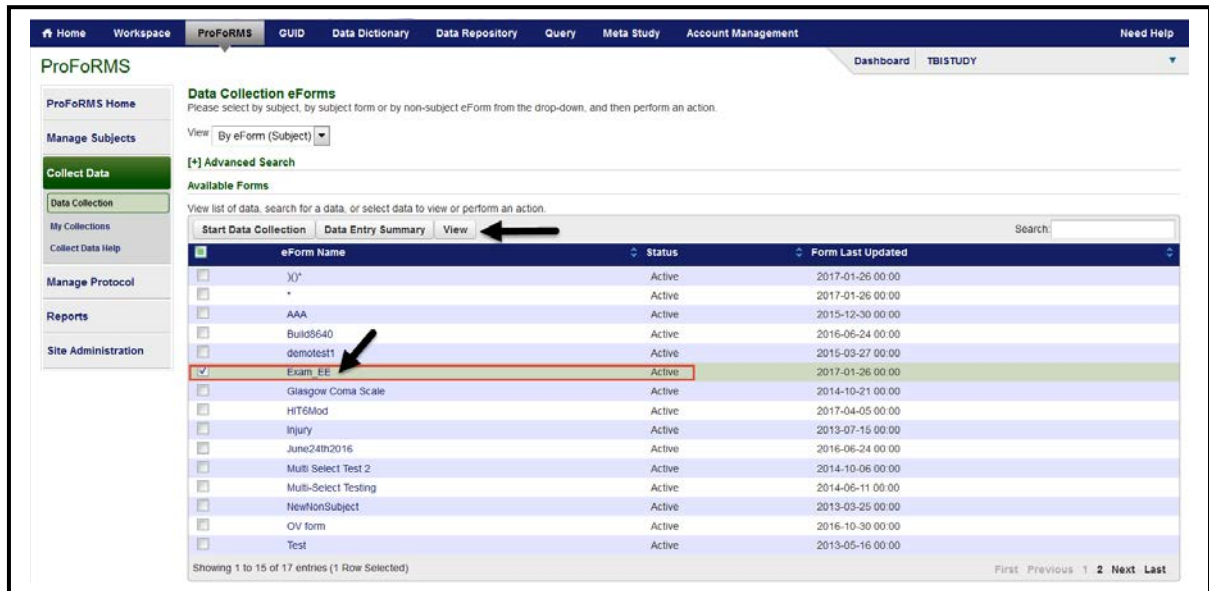
Start Data Collection | Data Entry Summary | View

eForm Name	Status	Form Last Updated
X0*	Active	2017-01-26 00:00
-	Active	2017-01-26 00:00
AAA	Active	2015-12-30 00:00
Build9640	Active	2016-06-24 00:00
demotest1	Active	2015-03-27 00:00
Exam_EE	Active	2017-01-26 00:00
Glasgow Coma Scale	Active	2014-10-21 00:00
HIT6Mod	Active	2017-04-05 00:00
Injury	Active	2013-07-15 00:00
June24th2016	Active	2016-06-24 00:00
Multi Select Test 2	Active	2014-10-06 00:00
Multi-Select Testing	Active	2014-06-11 00:00
NewNonSubject	Active	2013-03-25 00:00
OV form	Active	2016-10-30 00:00
Test	Active	2013-05-16 00:00

Showing 1 to 15 of 17 entries (0 Rows Selected)

First Previous 1 2 Next Last

- Click on the **eForms Name** OR Select the **Check-box** beside the eForm Name and Click the **View** button to open the **eForm** details;



ProFoRMS

Data Collection eForms
Please select by subject, by subject form or by non-subject eForm from the drop-down, and then perform an action.

View: By eForm (Subject) ▾

[+] Advanced Search

Available Forms
View list of data, search for a data, or select data to view or perform an action.

Start Data Collection | Data Entry Summary | **View** ←

<input type="checkbox"/>	eForm Name	Status	Form Last Updated
<input type="checkbox"/>	X0*	Active	2017-01-26 00:00
<input type="checkbox"/>	*	Active	2017-01-26 00:00
<input type="checkbox"/>	AAA	Active	2015-12-30 00:00
<input type="checkbox"/>	Build5640	Active	2016-06-24 00:00
<input type="checkbox"/>	demotest1	Active	2015-03-27 00:00
<input checked="" type="checkbox"/>	Exam_EE	Active	2017-01-26 00:00
<input type="checkbox"/>	Glasgow Coma Scale	Active	2014-10-21 00:00
<input type="checkbox"/>	HIT6Mod	Active	2017-04-05 00:00
<input type="checkbox"/>	Injury	Active	2013-07-15 00:00
<input type="checkbox"/>	June24th2016	Active	2016-06-24 00:00
<input type="checkbox"/>	Multi Select Test 2	Active	2014-10-06 00:00
<input type="checkbox"/>	Multi-Select Testing	Active	2014-06-11 00:00
<input type="checkbox"/>	NewNonSubject	Active	2013-03-25 00:00
<input type="checkbox"/>	OV form	Active	2016-10-30 00:00
<input type="checkbox"/>	Test	Active	2013-05-16 00:00

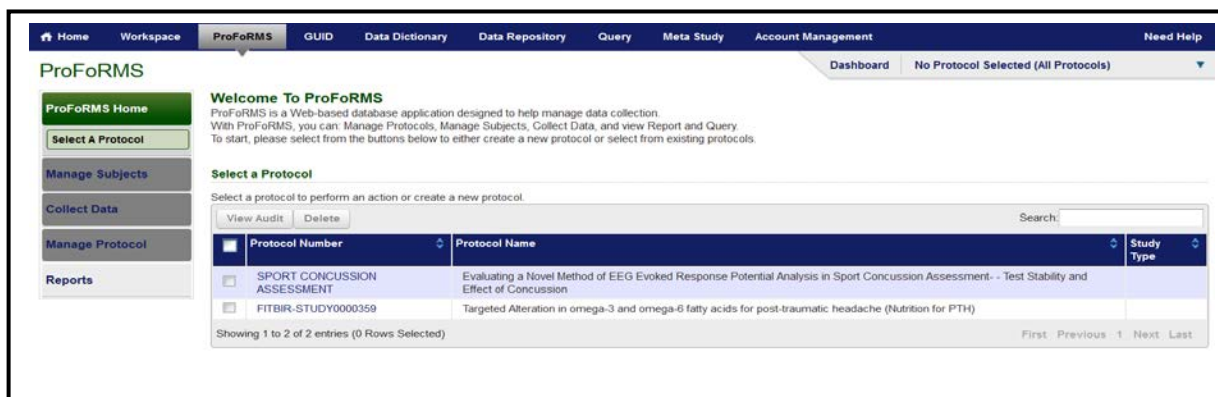
Showing 1 to 15 of 17 entries (1 Row Selected)

First Previous 1 2 Next Last

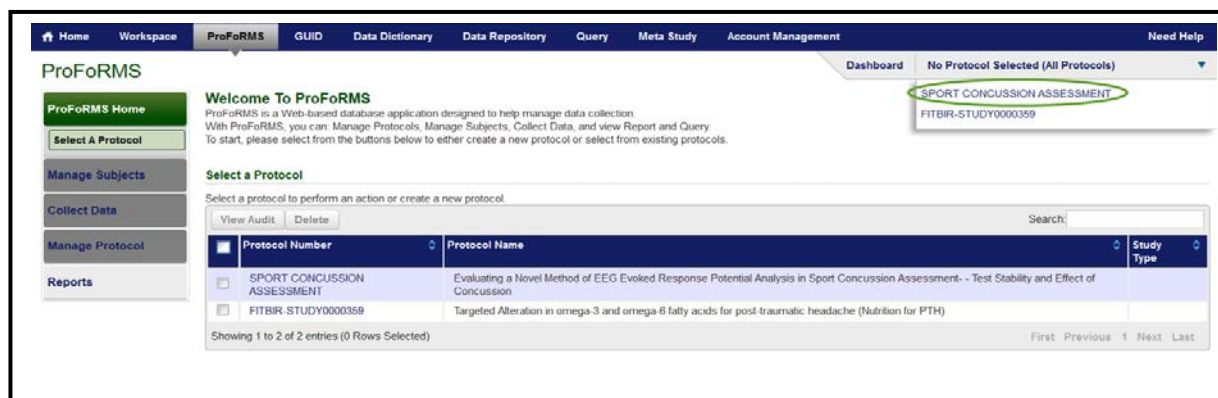
3.7.4 Viewing My Collections

To view data collections: Perform the following actions:

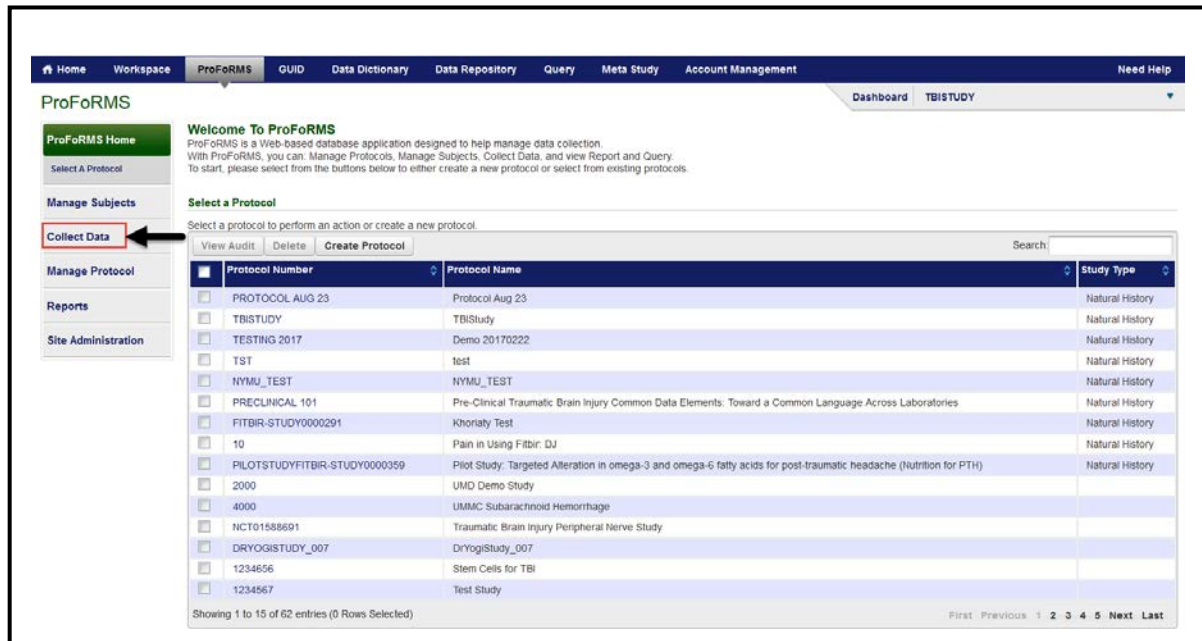
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



Welcome To ProFoRMS
ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol
Select a protocol to perform an action or create a new protocol.

View Audit | Delete | Create Protocol

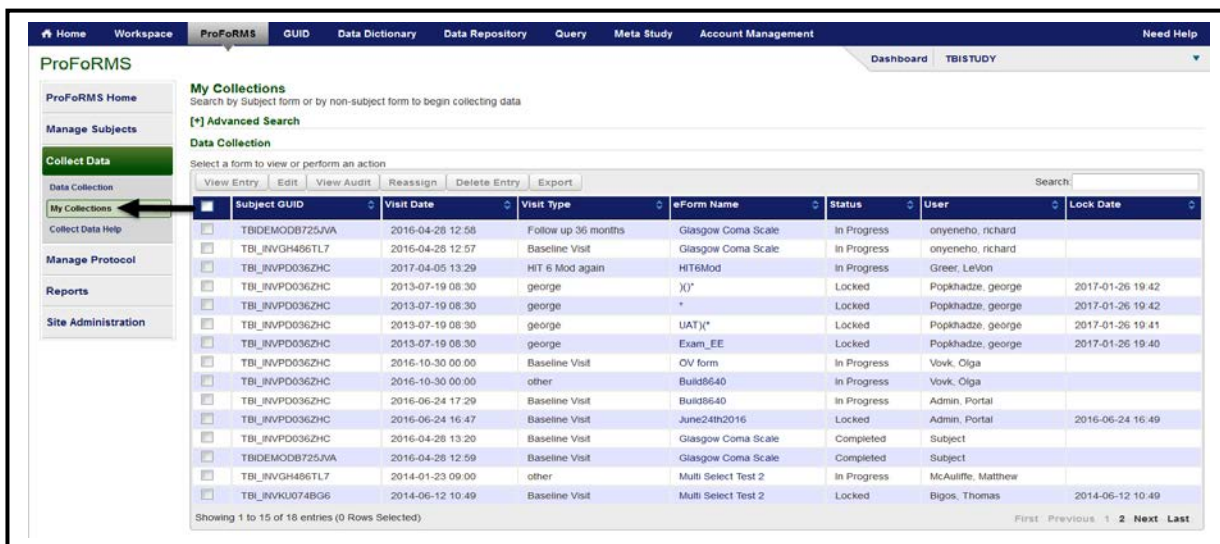
Protocol Number	Protocol Name	Study Type
PROTOCOL AUG 23	Protocol Aug 23	Natural History
TBISTUDY	TBIStudy	Natural History
TESTING 2017	Demo 20170222	Natural History
TST	test	Natural History
NYMU_TEST	NYMU_TEST	Natural History
PRECLINICAL 101	Pre-Clinical Traumatic Brain Injury Common Data Elements: Toward a Common Language Across Laboratories	Natural History
FITBIR-STUDY0000291	Khrona Test	Natural History
10	Pain in Using Fitbit: DJ	Natural History
PILOTSTUDYFITBIR-STUDY0000359	Pilot Study: Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Natural History
2000	UMD Demo Study	
4000	UMMC Subarachnoid Hemorrhage	
NCT01588691	Traumatic Brain Injury Peripheral Nerve Study	
DRYOGISTUDY_007	DRYogStudy_007	
1234565	Stem Cells for TBI	
1234567	Test Study	

Showing 1 to 15 of 62 entries (0 Rows Selected) First Previous 1 2 3 4 5 Next Last

4. Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, you can perform the following actions: **View Entry**, **Edit**, **View Audit**, **Reassign**, **Delete Entry** and **Export**

Note: Only the Non-Admin owner of collection OR ProFoRMS Admin/global Admin User will be able to edit an eform whose status is “in progress” or “complete”. Once the collection has been locked, nonadmin users will no longer be able to edit the eform.

When a user edits a completed form, an audit trail starts for any changed answers.



My Collections
Search by Subject form or by non-subject form to begin collecting data

[*] Advanced Search

Data Collection
Select a form to view or perform an action

View Entry | Edit | View Audit | Reassign | Delete Entry | Export

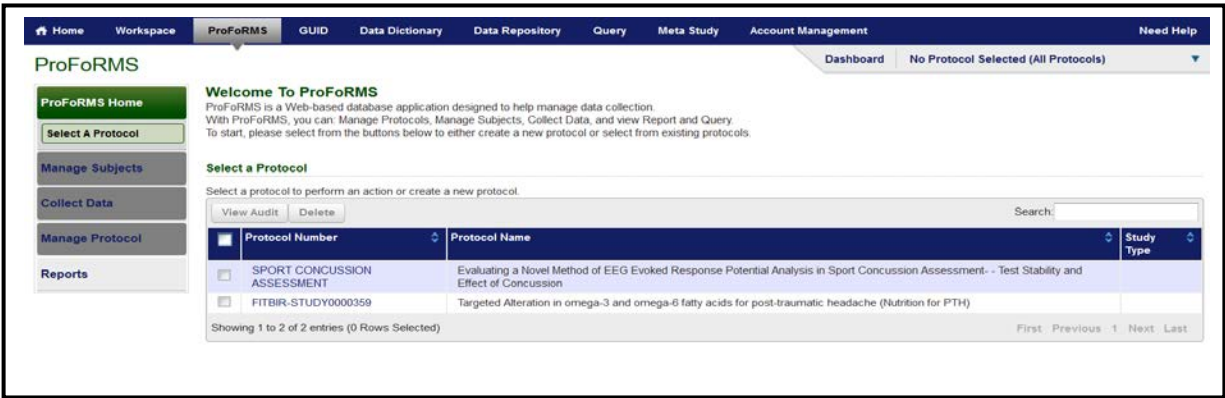
Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
TBIDEMOD8725JVA	2016-04-28 12:58	Follow up 36 months	Glasgow Coma Scale	In Progress	onyeneho, richard	
TBI_INVGH486TL7	2016-04-28 12:57	Baseline Visit	Glasgow Coma Scale	In Progress	onyeneho, richard	
TBI_INVPO036ZHC	2017-04-05 13:29	HIT 6 Mod again	HIT6Mod	In Progress	Greer, LeVon	
TBI_INVPO036ZHC	2013-07-19 08:30	george	XJ*	Locked	Popkhadze, george	2017-01-26 19:42
TBI_INVPO036ZHC	2013-07-19 08:30	george	*	Locked	Popkhadze, george	2017-01-26 19:42
TBI_INVPO036ZHC	2013-07-19 08:30	george	UATJ*	Locked	Popkhadze, george	2017-01-26 19:41
TBI_INVPO036ZHC	2013-07-19 08:30	george	Exam_EE	Locked	Popkhadze, george	2017-01-26 19:40
TBI_INVPO036ZHC	2016-10-30 00:00	Baseline Visit	OV form	In Progress	Vovk, Olga	
TBI_INVPO036ZHC	2016-10-30 00:00	other	Build640	In Progress	Vovk, Olga	
TBI_INVPO036ZHC	2016-06-24 17:29	Baseline Visit	Build640	In Progress	Admin, Portal	
TBI_INVPO036ZHC	2016-06-24 16:47	Baseline Visit	June24th2016	Locked	Admin, Portal	2016-06-24 16:49
TBI_INVPO036ZHC	2016-04-28 13:20	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
TBIDEMOD8725JVA	2016-04-28 12:59	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
TBI_INVGH486TL7	2014-01-23 09:00	other	Multi Select Test 2	In Progress	McAuliffe, Matthew	
TBI_INVKU074BG6	2014-06-12 10:49	Baseline Visit	Multi Select Test 2	Locked	Bigos, Thomas	2014-06-12 10:49

Showing 1 to 15 of 18 entries (0 Rows Selected) First Previous 1 2 Next Last

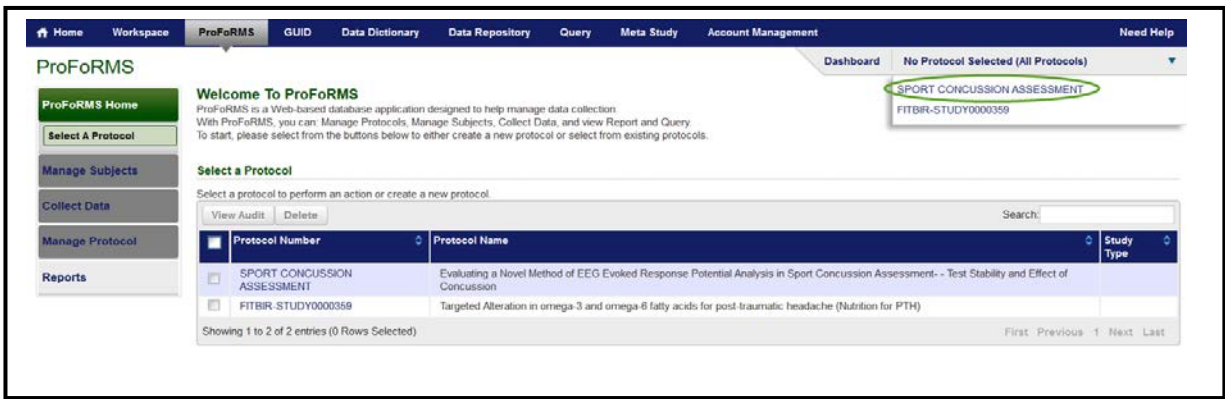
3.7.1 Reassigning Data Collections Entry Form

To reassign data collections entry form: Perform the following actions:

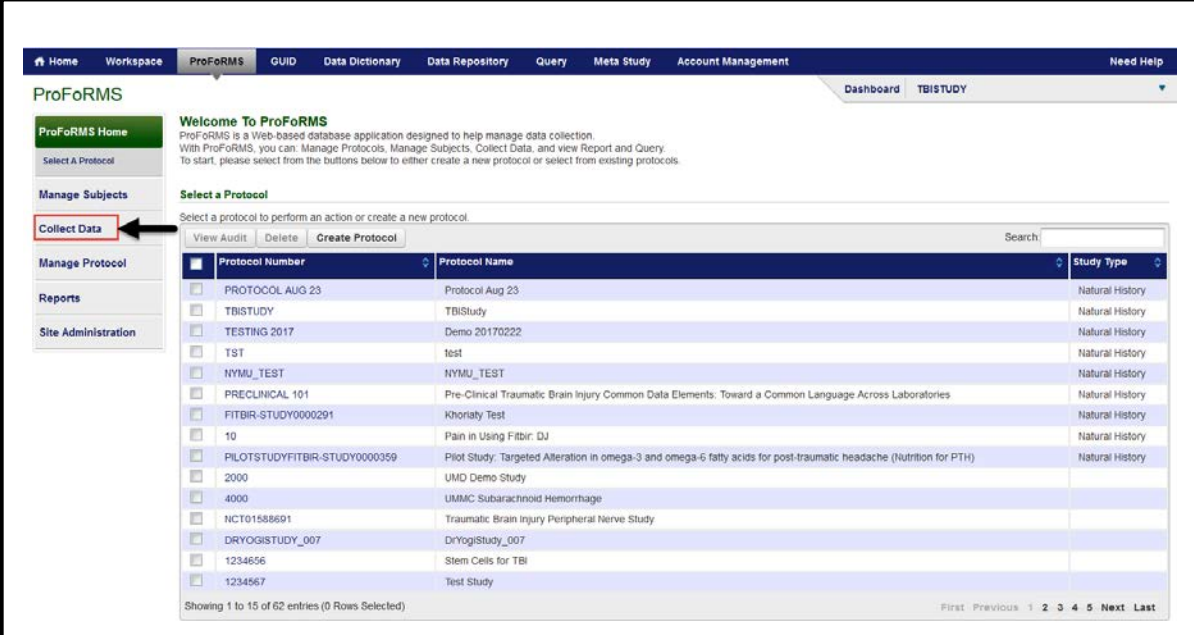
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Site Administration

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol.

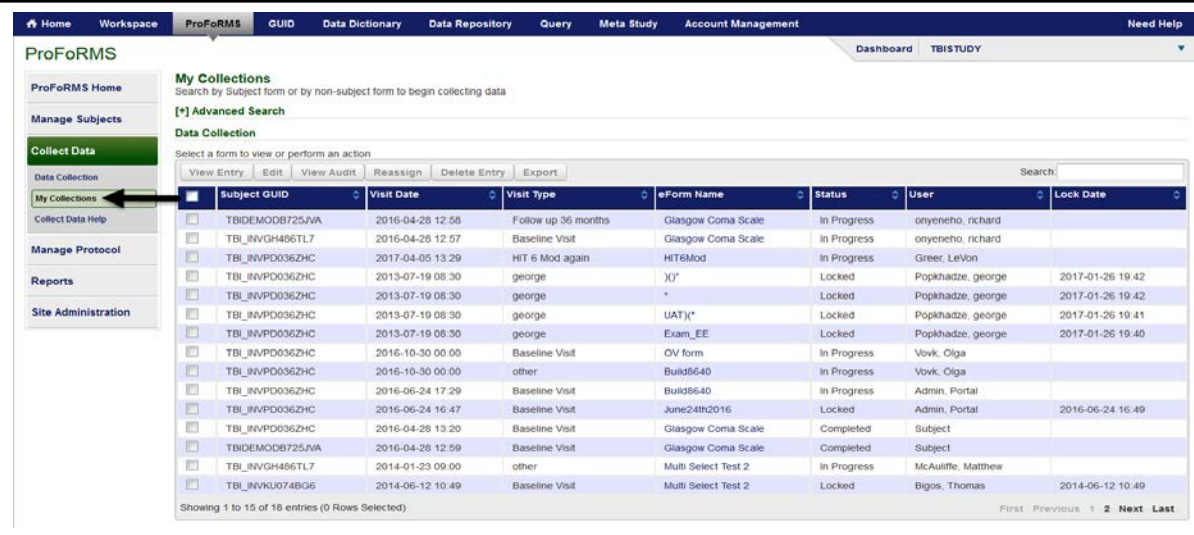
View Audit Delete Create Protocol

Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> PROTOCOL AUG 23	Protocol Aug 23	Natural History
<input type="checkbox"/> TBISTUDY	TBIStudy	Natural History
<input type="checkbox"/> TESTING 2017	Demo 20170222	Natural History
<input type="checkbox"/> TST	test	Natural History
<input type="checkbox"/> NYMU_TEST	NYMU_TEST	Natural History
<input type="checkbox"/> PRECLINICAL 101	Pre-Clinical Traumatic Brain Injury Common Data Elements: Toward a Common Language Across Laboratories	Natural History
<input type="checkbox"/> FITBIR-STUDY0000291	Khronaty Test	Natural History
<input type="checkbox"/> 10	Pain in Using Fitbir: DJ	Natural History
<input type="checkbox"/> PILOTSTUDYFITBIR-STUDY0000359	Pilot Study: Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Natural History
<input type="checkbox"/> 2000	UMD Demo Study	
<input type="checkbox"/> 4000	UMMC Subarachnoid Hemorrhage	
<input type="checkbox"/> NCT01588691	Traumatic Brain Injury Peripheral Nerve Study	
<input type="checkbox"/> DRYOGISTUDY_007	DRYogStudy_007	
<input type="checkbox"/> 1234565	Stem Cells for TBI	
<input type="checkbox"/> 1234567	Test Study	

Showing 1 to 15 of 62 entries (0 Rows Selected)

First Previous 1 2 3 4 5 Next Last

4. Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, you can perform the following actions: **View Entry, Edit, View Audit, Reassign, Delete Entry** and **Export**



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

ProFoRMS Home

Manage Subjects

Collect Data

Data Collection

My Collections

Collect Data Help

Manage Protocol

Reports

Site Administration

My Collections

Search by Subject form or by non-subject form to begin collecting data

[*] Advanced Search

Data Collection

Select a form to view or perform an action

View Entry Edit View Audit Reassign Delete Entry Export

Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
<input type="checkbox"/> TBIDEMOD8725JVA	2016-04-28 12:58	Follow up 36 months	Glasgow Coma Scale	In Progress	onyeneho, richard	
<input type="checkbox"/> TBI_INVGH486TL7	2016-04-28 12:57	Baseline Visit	Glasgow Coma Scale	In Progress	onyeneho, richard	
<input type="checkbox"/> TBI_INVPO036ZHC	2017-04-05 13:29	HIT 6 Mod again	HIT6Mod	In Progress	Greer, LeVon	
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	XJ*	Locked	Popkhadze, george	2017-01-26 19:42
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	*	Locked	Popkhadze, george	2017-01-26 19:42
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	UATJ*	Locked	Popkhadze, george	2017-01-26 19:41
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	Exam_EE	Locked	Popkhadze, george	2017-01-26 19:40
<input type="checkbox"/> TBI_INVPO036ZHC	2016-10-30 00:00	Baseline Visit	OV form	In Progress	Vovk, Olga	
<input type="checkbox"/> TBI_INVPO036ZHC	2016-10-30 00:00	other	Buid8640	In Progress	Vovk, Olga	
<input type="checkbox"/> TBI_INVPO036ZHC	2016-06-24 17:29	Baseline Visit	Buid8640	In Progress	Admin, Portal	
<input type="checkbox"/> TBI_INVPO036ZHC	2016-06-24 16:47	Baseline Visit	June24th2016	Locked	Admin, Portal	2016-06-24 16:49
<input type="checkbox"/> TBI_INVPO036ZHC	2016-04-28 13:20	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
<input type="checkbox"/> TBIDEMOD8725JVA	2016-04-28 12:59	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
<input type="checkbox"/> TBI_INVGH486TL7	2014-01-23 09:00	other	Multi Select Test 2	In Progress	McAuliffe, Matthew	
<input type="checkbox"/> TBI_INVKU074BG6	2014-06-12 10:49	Baseline Visit	Multi Select Test 2	Locked	Bigos, Thomas	2014-06-12 10:49

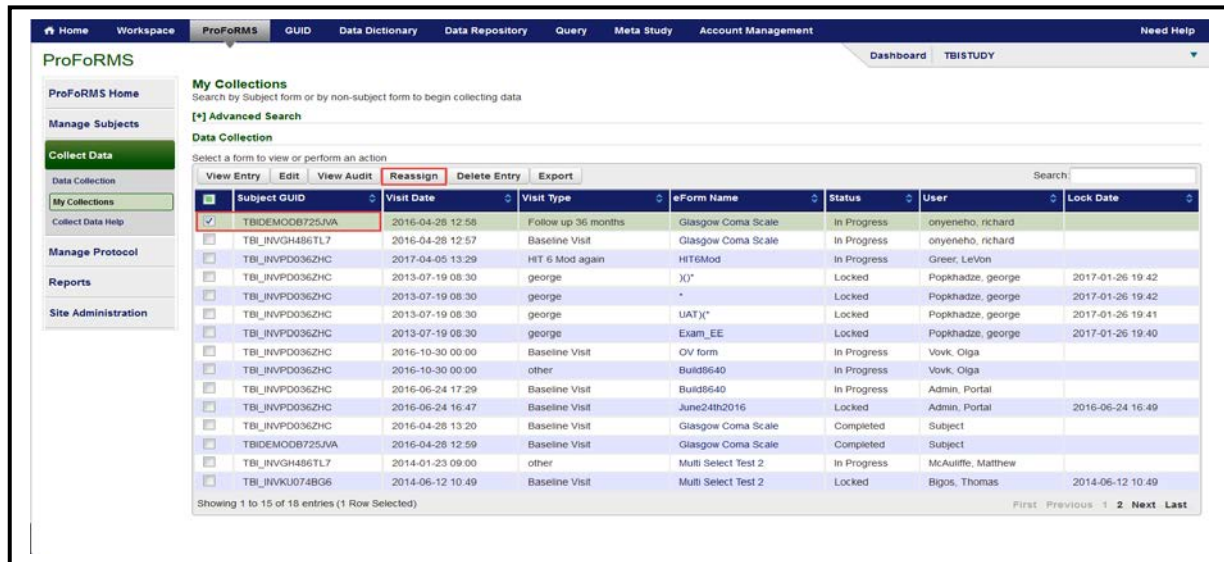
Showing 1 to 15 of 18 entries (0 Rows Selected)

First Previous 1 2 Next Last

5. Select the Check-box next to the Subject you would like to reassign. **Note:** The ability to assign the form to another user for editing are limited to:

- *Global Admin Users,*
- *Non-Admin Users with Primary Investigator (PI) Role,*
- *Non-Admin Users with Clinical Coordinators Role,*
- *Non-Admin Users with Study QA Role, and*

- *Non- Admin Users with a role that has the privileges to Reassign Data Entry.*



ProFoRMS

My Collections
Search by Subject form or by non-subject form to begin collecting data

[+] Advanced Search

Data Collection
Select a form to view or perform an action

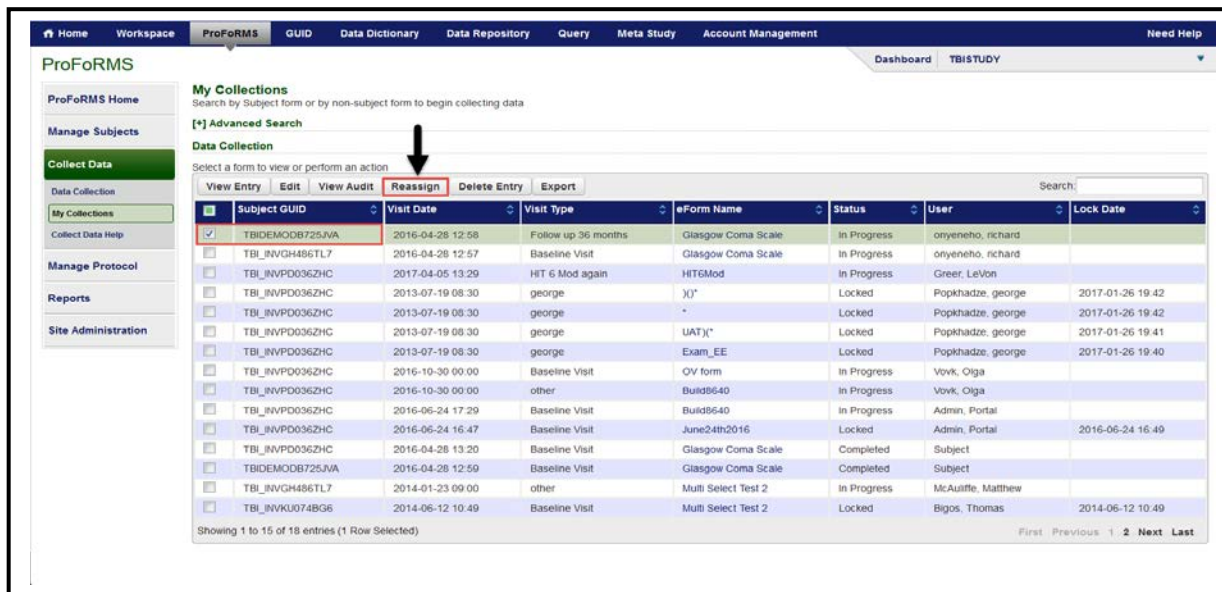
View Entry Edit View Audit **Reassign** Delete Entry Export

Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
<input checked="" type="checkbox"/> TBIDEMO08725JVA	2016-04-28 12:58	Follow up 36 months	Glasgow Coma Scale	In Progress	onyeneho, richard	
<input type="checkbox"/> TBI_INVGH486TL7	2016-04-28 12:57	Baseline Visit	Glasgow Coma Scale	In Progress	onyeneho, richard	
<input type="checkbox"/> TBI_INVPO036ZHC	2017-04-05 13:29	HIT 6 Mod again	HIT6Mod	In Progress	Greer, LeVon	
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	XJ*	Locked	Popkhadze, george	2017-01-26 19:42
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	*	Locked	Popkhadze, george	2017-01-26 19:42
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	UATJ(*)	Locked	Popkhadze, george	2017-01-26 19:41
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	Exam_EE	Locked	Popkhadze, george	2017-01-26 19:40
<input type="checkbox"/> TBI_INVPO036ZHC	2016-10-30 00:00	Baseline Visit	OV form	In Progress	Vovk, Olga	
<input type="checkbox"/> TBI_INVPO036ZHC	2016-10-30 00:00	other	Build9640	In Progress	Vovk, Olga	
<input type="checkbox"/> TBI_INVPO036ZHC	2016-06-24 17:29	Baseline Visit	Build9640	In Progress	Admin, Portal	
<input type="checkbox"/> TBI_INVPO036ZHC	2016-06-24 16:47	Baseline Visit	June24th2016	Locked	Admin, Portal	2016-06-24 16:49
<input type="checkbox"/> TBI_INVPO036ZHC	2016-04-28 13:20	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
<input type="checkbox"/> TBIDEMO08725JVA	2016-04-28 12:59	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
<input type="checkbox"/> TBI_INVGH486TL7	2014-01-23 09:00	other	Multi Select Test 2	In Progress	McAuliffe, Matthew	
<input type="checkbox"/> TBI_INVKU074BG6	2014-06-12 10:49	Baseline Visit	Multi Select Test 2	Locked	Bigos, Thomas	2014-06-12 10:49

Showing 1 to 15 of 18 entries (1 Row Selected)

First Previous 1 2 Next Last

6. Click the **Re-assign** button. The **Reassign Data Entry** page appear.



ProFoRMS

My Collections
Search by Subject form or by non-subject form to begin collecting data

[+] Advanced Search

Data Collection
Select a form to view or perform an action

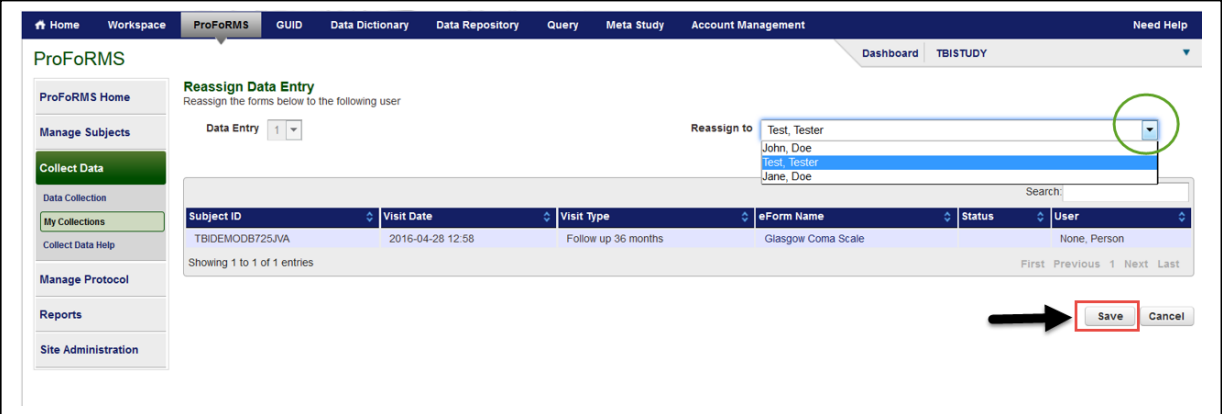
View Entry Edit View Audit **Reassign** Delete Entry Export

Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
<input checked="" type="checkbox"/> TBIDEMO08725JVA	2016-04-28 12:58	Follow up 36 months	Glasgow Coma Scale	In Progress	onyeneho, richard	
<input type="checkbox"/> TBI_INVGH486TL7	2016-04-28 12:57	Baseline Visit	Glasgow Coma Scale	In Progress	onyeneho, richard	
<input type="checkbox"/> TBI_INVPO036ZHC	2017-04-05 13:29	HIT 6 Mod again	HIT6Mod	In Progress	Greer, LeVon	
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	XJ*	Locked	Popkhadze, george	2017-01-26 19:42
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	*	Locked	Popkhadze, george	2017-01-26 19:42
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	UATJ(*)	Locked	Popkhadze, george	2017-01-26 19:41
<input type="checkbox"/> TBI_INVPO036ZHC	2013-07-19 08:30	george	Exam_EE	Locked	Popkhadze, george	2017-01-26 19:40
<input type="checkbox"/> TBI_INVPO036ZHC	2016-10-30 00:00	Baseline Visit	OV form	In Progress	Vovk, Olga	
<input type="checkbox"/> TBI_INVPO036ZHC	2016-10-30 00:00	other	Build9640	In Progress	Vovk, Olga	
<input type="checkbox"/> TBI_INVPO036ZHC	2016-06-24 17:29	Baseline Visit	Build9640	In Progress	Admin, Portal	
<input type="checkbox"/> TBI_INVPO036ZHC	2016-06-24 16:47	Baseline Visit	June24th2016	Locked	Admin, Portal	2016-06-24 16:49
<input type="checkbox"/> TBI_INVPO036ZHC	2016-04-28 13:20	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
<input type="checkbox"/> TBIDEMO08725JVA	2016-04-28 12:59	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
<input type="checkbox"/> TBI_INVGH486TL7	2014-01-23 09:00	other	Multi Select Test 2	In Progress	McAuliffe, Matthew	
<input type="checkbox"/> TBI_INVKU074BG6	2014-06-12 10:49	Baseline Visit	Multi Select Test 2	Locked	Bigos, Thomas	2014-06-12 10:49

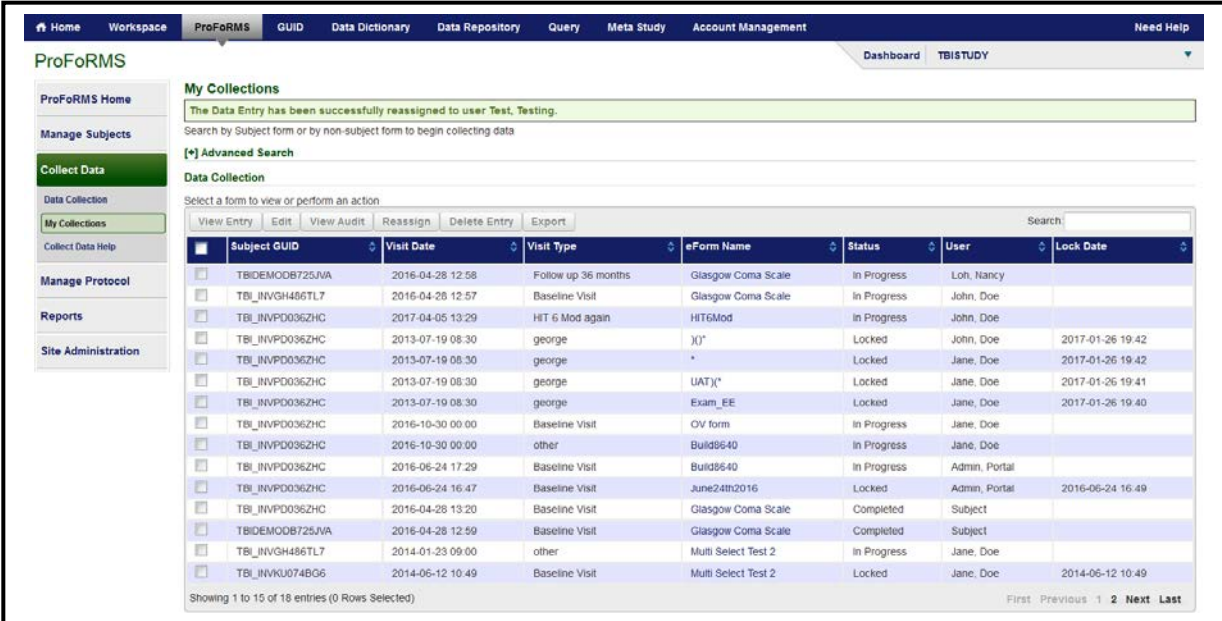
Showing 1 to 15 of 18 entries (1 Row Selected)

First Previous 1 2 Next Last

- Using the drop-down menu, select the desired user to reassign the form. Click the **Save** button.



- The **My Collections** page appears with the reassigned form updated.

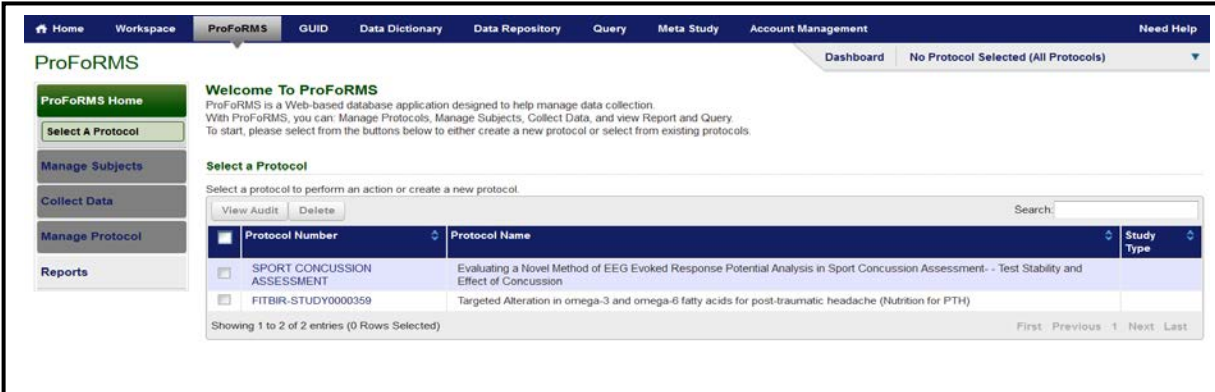


Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
TBIDEMO08725JVA	2016-04-28 12:58	Follow up 36 months	Glasgow Coma Scale	In Progress	Loh, Nancy	
TBI_INVGH486TL7	2016-04-28 12:57	Baseline Visit	Glasgow Coma Scale	In Progress	John, Doe	
TBI_INVPO036ZHC	2017-04-05 13:29	HIT 6 Mod again	HIT6Mod	In Progress	John, Doe	
TBI_INVPO036ZHC	2013-07-19 08:30	george	XJ)	Locked	John, Doe	2017-01-26 19:42
TBI_INVPO036ZHC	2013-07-19 08:30	george	*	Locked	Jane, Doe	2017-01-26 19:42
TBI_INVPO036ZHC	2013-07-19 08:30	george	UATX)	Locked	Jane, Doe	2017-01-26 19:41
TBI_INVPO036ZHC	2013-07-19 08:30	george	Exam_EE	Locked	Jane, Doe	2017-01-26 19:40
TBI_INVPO036ZHC	2016-10-30 00:00	Baseline Visit	OV form	In Progress	Jane, Doe	
TBI_INVPO036ZHC	2016-10-30 00:00	other	Build9640	In Progress	Jane, Doe	
TBI_INVPO036ZHC	2016-06-24 17:29	Baseline Visit	Build9640	In Progress	Admin, Portal	
TBI_INVPO036ZHC	2016-06-24 16:47	Baseline Visit	June24th2016	Locked	Admin, Portal	2016-06-24 16:49
TBI_INVPO036ZHC	2016-04-28 13:20	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
TBIDEMO08725JVA	2016-04-28 12:59	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
TBI_INVGH486TL7	2014-01-23 09:00	other	Multi Select Test 2	In Progress	Jane, Doe	
TBI_INVK074B06	2014-06-12 10:49	Baseline Visit	Multi Select Test 2	Locked	Jane, Doe	2014-06-12 10:49

3.7.2 Viewing eForm Information

To view **eForm Information**: Perform the following actions:

1. Navigate to the **ProFoRMS** module



ProFoRMS

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

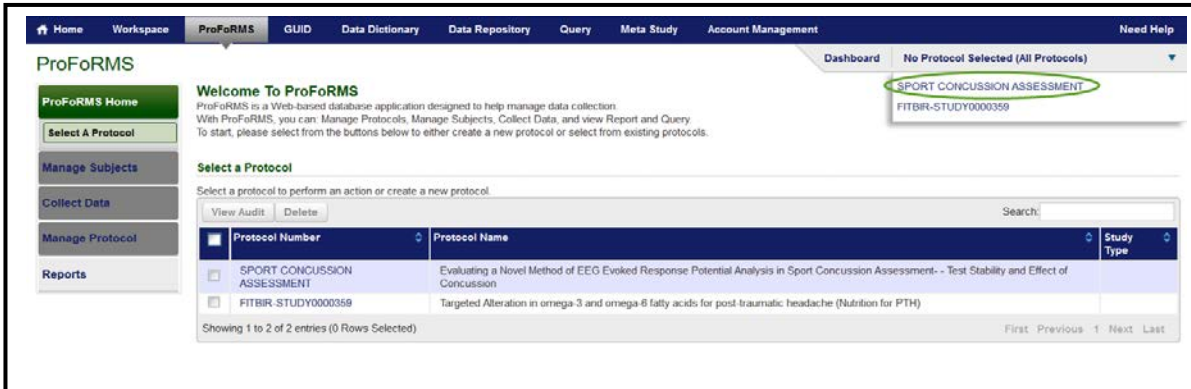
Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
<input type="checkbox"/> FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



ProFoRMS

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
<input type="checkbox"/> FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TBISTUDY

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Site Administration

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol.

View Audit>Delete>Create Protocol

Search:

Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> PROTOCOL AUG 23	Protocol Aug 23	Natural History
<input type="checkbox"/> TBISTUDY	TBIStudy	Natural History
<input type="checkbox"/> TESTING 2017	Demo 20170222	Natural History
<input type="checkbox"/> TST	test	Natural History
<input type="checkbox"/> NYMU_TEST	NYMU_TEST	Natural History
<input type="checkbox"/> PRECLINICAL 101	Pre-Clinical Traumatic Brain Injury Common Data Elements: Toward a Common Language Across Laboratories	Natural History
<input type="checkbox"/> FITBIR-STUDY0000291	Khronaty Test	Natural History
<input type="checkbox"/> 10	Pain in Using Fitbir: DJ	Natural History
<input type="checkbox"/> PILOTSTUDYFITBIR-STUDY0000359	Pilot Study: Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Natural History
<input type="checkbox"/> 2000	UMD Demo Study	
<input type="checkbox"/> 4000	UMMC Subarachnoid Hemorrhage	
<input type="checkbox"/> NCT01588691	Traumatic Brain Injury Peripheral Nerve Study	
<input type="checkbox"/> DRYOGISTUDY_007	DrYogStudy_007	
<input type="checkbox"/> 1234565	Stem Cells for TBI	
<input type="checkbox"/> 1234567	Test Study	

Showing 1 to 15 of 62 entries (0 Rows Selected)First Previous 1 2 3 4 5 Next Last

4. Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, Click the **View Entry** button.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

TBISTUDY

ProFoRMS Home

Manage Subjects

Collect Data

My Collections

Data Collection

Collect Data Help

Manage Protocol

Reports

Site Administration

My Collections

Search by Subject form or by non-subject form to begin collecting data

[*] Advanced Search

Data Collection

Select a form to view or perform an action

View Entry>EditView AuditReassignDelete EntryExport

Search:

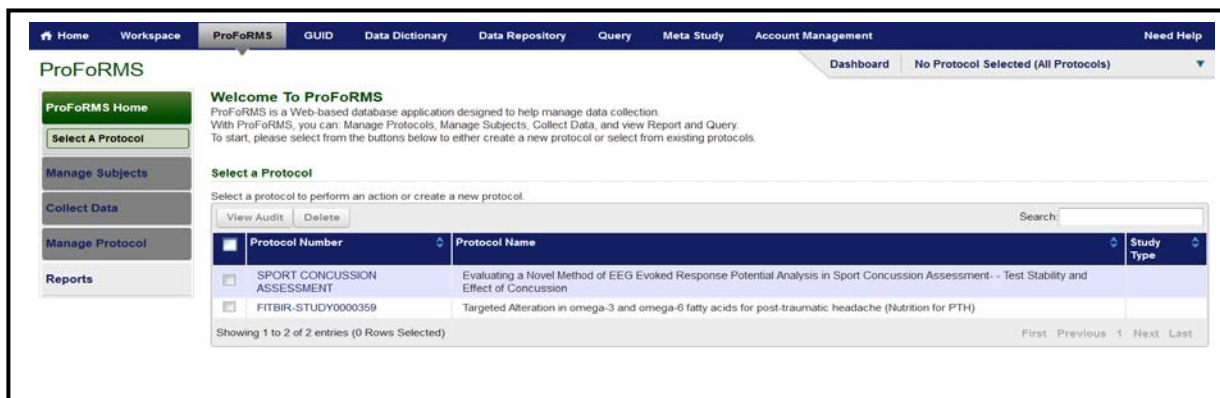
Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
<input type="checkbox"/> TBI_INVGH486TL7	2014-06-12 10:40	Baseline Visit	Multi Select Test 2	Locked	Jon. Doe	2014-06-12 10:41
<input checked="" type="checkbox"/> TBI_INVPO036ZHC	2014-06-12 10:10	Baseline Visit	Multi Select Test 2	Locked	Jon. Doe	2014-06-12 10:10
<input type="checkbox"/> TBIDEM08725JVA	2014-06-11 14:05	Baseline Visit	Multi Select Test 2	Locked	Jon. Doe	2014-06-11 14:05

Showing 16 to 18 of 18 entries (1 Row Selected)First Previous 1 2 Next Last

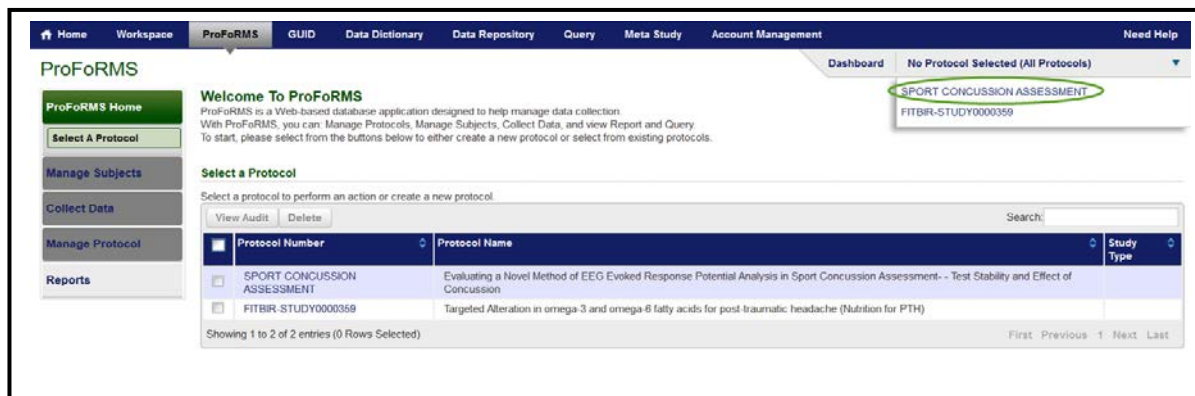
3.7.1 Deleting My Collections

To Delete Data Entry eForm: Perform the following actions:

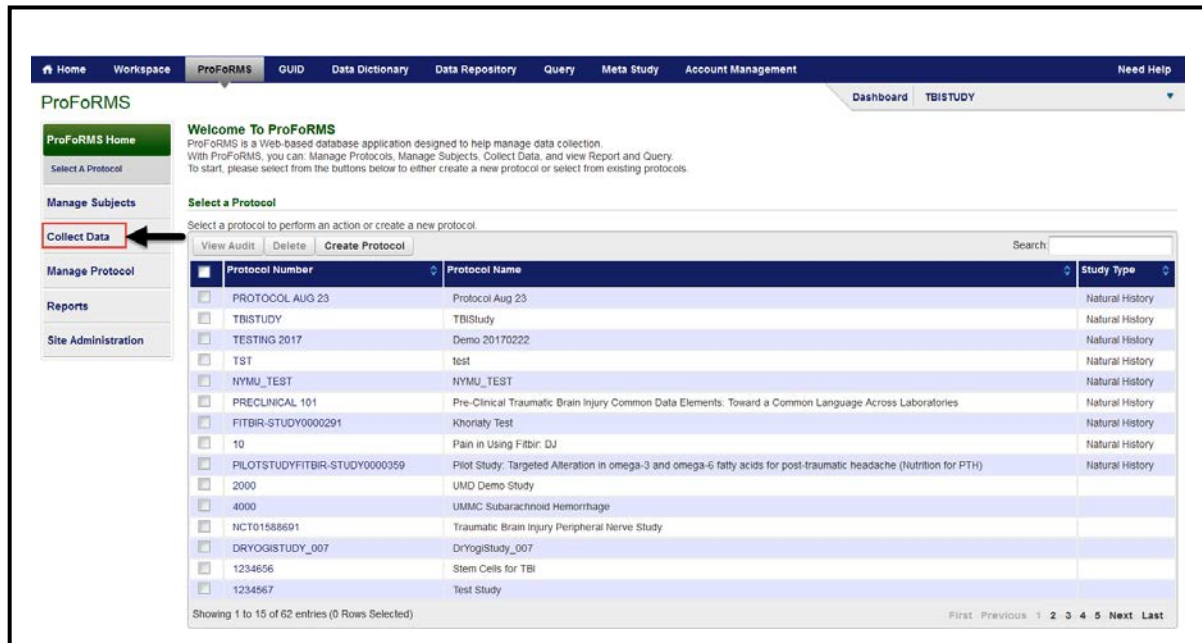
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



Welcome To ProFoRMS
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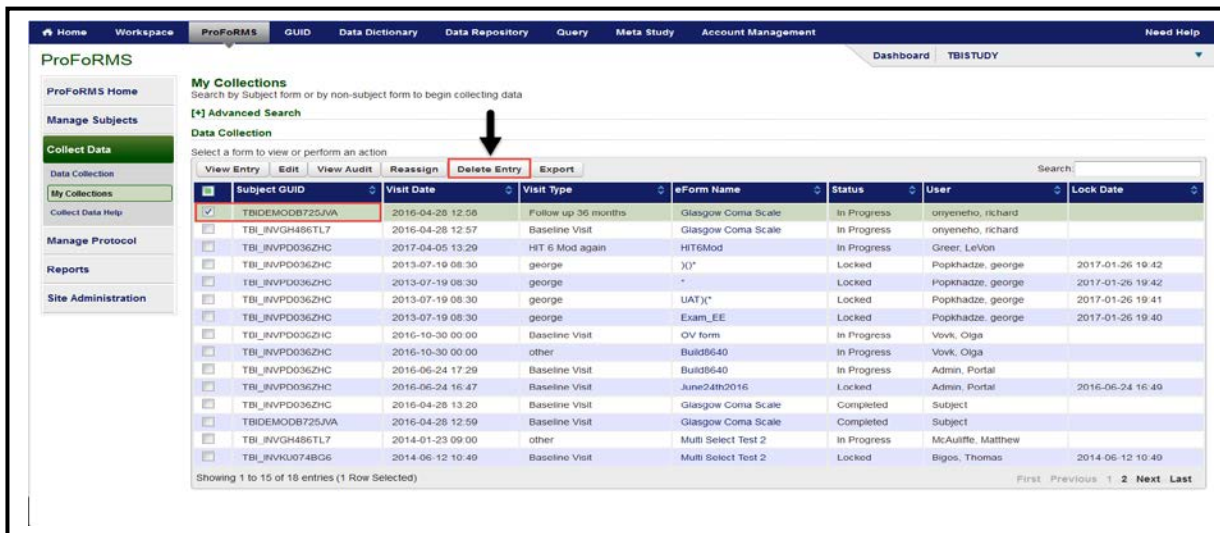
Select a Protocol
Select a protocol to perform an action or create a new protocol.

View Audit Delete Create Protocol

Protocol Number	Protocol Name	Study Type
PROTOCOL AUG 23	Protocol Aug 23	Natural History
TBISTUDY	TBIStudy	Natural History
TESTING 2017	Demo 20170222	Natural History
TST	test	Natural History
NYMU_TEST	NYMU_TEST	Natural History
PRECLINICAL 101	Pre-Clinical Traumatic Brain Injury Common Data Elements: Toward a Common Language Across Laboratories	Natural History
FITBIR-STUDY0000291	Khrona Test	Natural History
10	Pain in Using Fitbir: DJ	Natural History
PILOTSTUDYFITBIR-STUDY0000359	Pilot Study: Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Natural History
2000	UMD Demo Study	
4000	UMAC Subarachnoid Hemorrhage	
NCT01588691	Traumatic Brain Injury Peripheral Nerve Study	
DRYOGISTUDY_007	DryogStudy_007	
1234565	Stem Cells for TBI	
1234567	Test Study	

Showing 1 to 15 of 62 entries (0 Rows Selected) First Previous 1 2 3 4 5 Next Last

4. Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, select the Check-box next to the Subject you would like to delete. Click the **Delete Entry** button.



My Collections
Search by Subject form or by non-subject form to begin collecting data

[+] Advanced Search

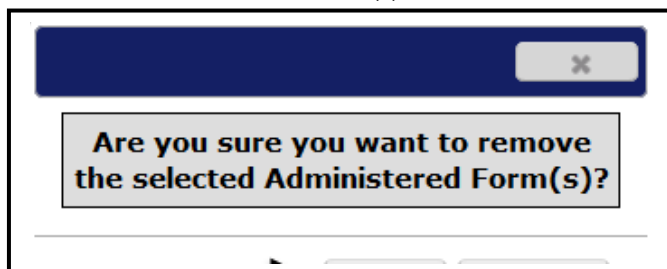
Data Collection
Select a form to view or perform an action

View Entry Edit View Audit Reassign Delete Entry Export

Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
<input checked="" type="checkbox"/> TBIDEMODB725JVA	2016-04-26 12:56	Follow up 36 months	Glasgow Coma Scale	In Progress	brayenro, richard	
<input type="checkbox"/> TBI_RVGH486TL7	2016-04-26 12:57	Baseline Visit	Glasgow Coma Scale	In Progress	onyeneho, richard	
<input type="checkbox"/> TBI_RVDP036ZHC	2017-04-05 13:29	HT 6 Mod again	HT6Mod	In Progress	Greer, LeVon	
<input type="checkbox"/> TBI_RVDP036ZHC	2013-07-19 08:30	george	XI*	Locked	Popkhadze, george	2017-01-26 19:42
<input type="checkbox"/> TBI_RVDP036ZHC	2013-07-19 08:30	george	-	Locked	Popkhadze, george	2017-01-26 19:42
<input type="checkbox"/> TBI_RVDP036ZHC	2013-07-19 08:30	george	UATjx*	Locked	Popkhadze, george	2017-01-26 19:41
<input type="checkbox"/> TBI_RVDP036ZHC	2013-07-19 08:30	george	Exam_EE	Locked	Popkhadze, george	2017-01-26 19:40
<input type="checkbox"/> TBI_RVDP036ZHC	2016-10-30 00:00	Baseline Visit	OV form	In Progress	Vovk, Olga	
<input type="checkbox"/> TBI_RVDP036ZHC	2016-10-30 00:00	other	Build8640	In Progress	Vovk, Olga	
<input type="checkbox"/> TBI_RVDP036ZHC	2016-06-24 17:29	Baseline Visit	Build8640	In Progress	Admin, Portal	
<input type="checkbox"/> TBI_RVDP036ZHC	2016-06-24 16:47	Baseline Visit	June24th2016	Locked	Admin, Portal	2016-06-24 16:49
<input type="checkbox"/> TBI_RVDP036ZHC	2016-04-26 13:20	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
<input type="checkbox"/> TBIDEMODB725JVA	2016-04-26 12:59	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
<input type="checkbox"/> TBI_RVGH486TL7	2014-01-23 09:00	other	Multi Select Test 2	In Progress	McAuliffe, Matthew	
<input type="checkbox"/> TBI_RVKK0748G6	2014-06-12 10:49	Baseline Visit	Multi Select Test 2	Locked	Bigos, Thomas	2014-06-12 10:49

Showing 1 to 15 of 18 entries (1 Row Selected) First Previous 1 2 Next Last



- Click the **OK** button when prompted ‘Are you sure you want to remove the selected Administered Form(s)?’



- The **My Collections** page appears with the confirmation of the deleted Data Entry form updated.














Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
TBIDEMO08725/NA	2016-04-28 12:58	Follow up 36 months	Glasgow Coma Scale	In Progress	Jane, Doe	
TBI_INVGH486TL7	2016-04-28 12:57	Baseline Visit	Glasgow Coma Scale	In Progress	Jane, Doe	
TBI_INVPD036ZHC	2017-04-05 13:29	HIT 6 Mod again	HIT6Mod	In Progress	Jane, Doe	
TBI_INVPD036ZHC	2013-07-19 08:30	george	X0*	Locked	Jane, Doe	2017-01-26 19:42
TBI_INVPD036ZHC	2013-07-19 08:30	george	*	Locked	Jane, Doe	2017-01-26 19:42
TBI_INVPD036ZHC	2013-07-19 08:30	george	Exam_EE	Locked	Jane, Doe	2017-01-26 19:40
TBI_INVPD036ZHC	2016-10-30 00:00	Baseline Visit	Ov form	In Progress	Jane, Doe	
TBI_INVPD036ZHC	2016-10-30 00:00	other	Bukd8640	In Progress	Jane, Doe	
TBI_INVPD036ZHC	2016-06-24 17:29	Baseline Visit	Bukd8640	In Progress	Admin, Portal	
TBI_INVPD036ZHC	2016-06-24 16:47	Baseline Visit	June24th2016	Locked	Admin, Portal	2016-06-24 16:49
TBI_INVPD036ZHC	2016-04-28 13:20	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
TBIDEMO08725/NA	2016-04-28 12:58	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
TBI_INVGH486TL7	2014-01-23 09:00	other	Multi Select Test 2	In Progress	Jane, Doe	
TBI_INVKU074BG6	2014-06-12 10:49	Baseline Visit	Multi Select Test 2	Locked	Jane, Doe	2014-06-12 10:49
TBI_INVGH486TL7	2014-06-12 10:40	Baseline Visit	Multi Select Test 2	Locked	Bigos, Thomas	2014-06-12 10:41

ICON KEY

-  Notes
-  Important Information

Things to Note:

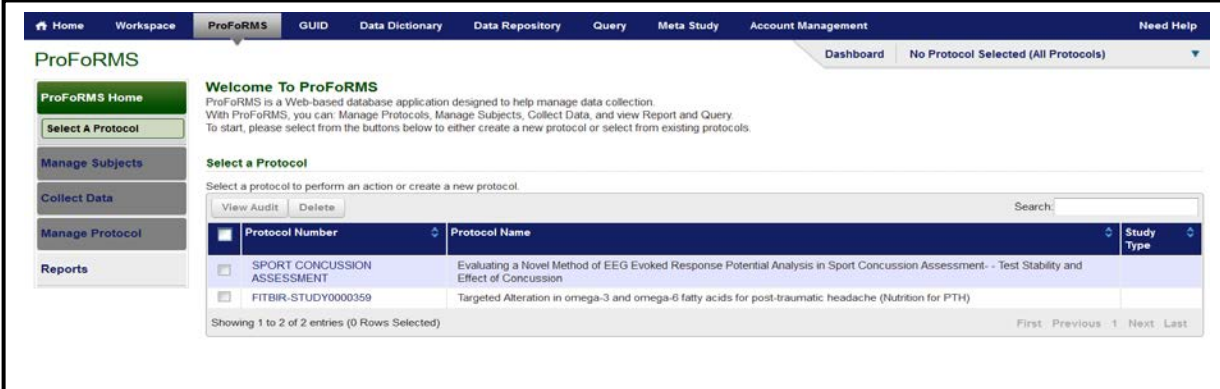
Below details the different scenarios and users who have the ability to delete a data collection:

-  **In Progress Status:**
 -  Global Admin
 -  ProFoRMS Admin
 -  Nonadmin users with privileges to delete collections
 -  Owners of the data collection
-  **Completed Status:**
 -  Global Admin
 -  ProFoRMS Admin
 -  Nonadmin users with privileges to delete collections
 -  Owners of Data Collection
-  **Locked Status:**
 -  Global Admin
 -  ProFoRMS Admin

3.7.2 Exporting Data Collections

To Export Data Collections: Perform the following actions:

1. Navigate to the **ProFoRMS** module



ProFoRMS

Welcome To ProFoRMS

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Select a Protocol

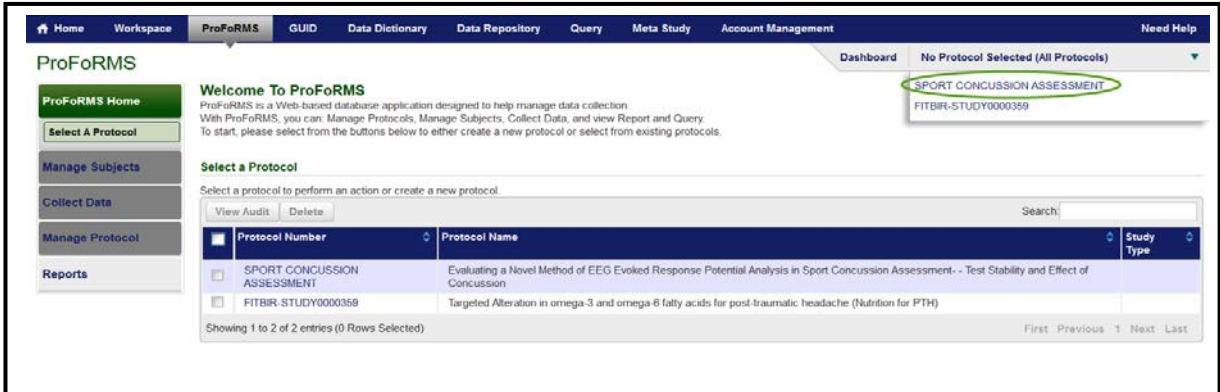
Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



ProFoRMS

Welcome To ProFoRMS

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Select a Protocol

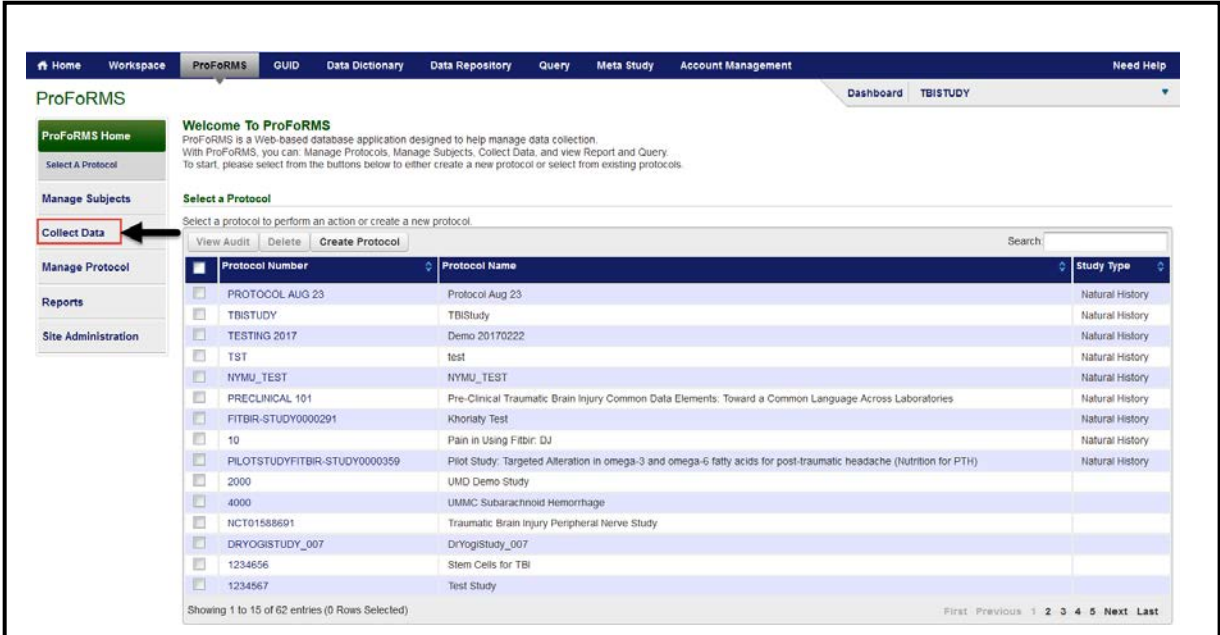
Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



ProFoRMS

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

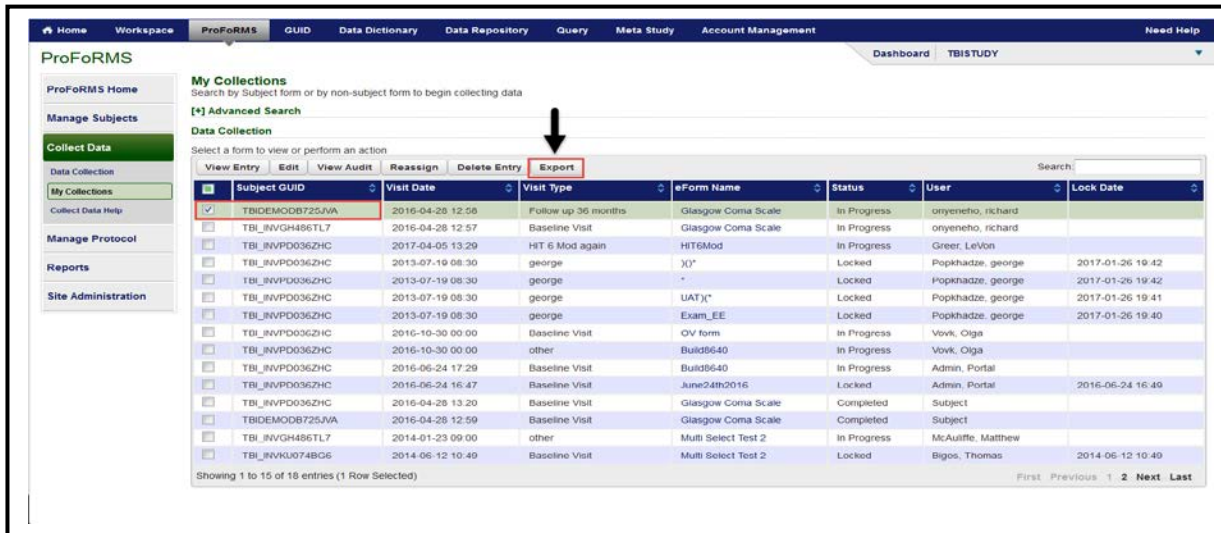
Select a protocol to perform an action or create a new protocol.

View Audit Delete Create Protocol Search:

Protocol Number	Protocol Name	Study Type
PROTOCOL AUG 23	Protocol Aug 23	Natural History
TBI STUDY	TBI Study	Natural History
TESTING 2017	Demo 20170222	Natural History
TST	test	Natural History
NYMU_TEST	NYMU_TEST	Natural History
PRECLINICAL 101	Pre-Clinical Traumatic Brain Injury Common Data Elements: Toward a Common Language Across Laboratories	Natural History
FITBIR-STUDY0000291	Khoraly Test	Natural History
10	Pain in Using Fitbir: DJ	Natural History
PILOTSTUDYFITBIR-STUDY0000359	Pilot Study: Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Natural History
2000	UMD Demo Study	
4000	UMMC Subarachnoid Hemorrhage	
NCT01585691	Traumatic Brain Injury Peripheral Nerve Study	
DRYOGISTUDY_007	DRYOGISTUDY_007	
1234565	Stem Cells for TBI	
1234567	Test Study	

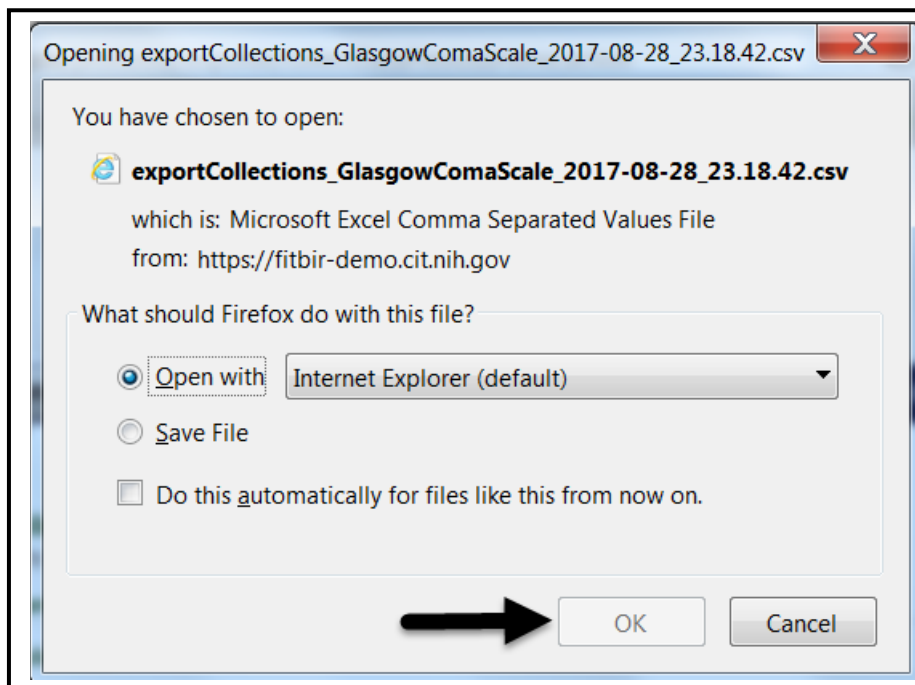
Showing 1 to 15 of 62 entries (0 Rows Selected) First Previous 1 2 3 4 5 Next Last

- Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, select the Check-box next to the Subject you would like to export. Click the **Export Entry** button.




Subject GUID	Visit Date	Visit Type	eForm Name	Status	User	Lock Date
TBIDEMOD8725JVA	2016-04-28 12:58	Follow up 36 months	Glasgow Coma Scale	In Progress	onyeneto, richard	
TBI_RVGH486TL7	2016-04-28 12:57	Baseline Visit	Glasgow Coma Scale	In Progress	onyeneto, richard	
TBI_RVDP036ZHC	2017-04-05 13:29	HT 6 Mod again	HT6Mod	In Progress	Greer, LeVon	
TBI_RVDP036ZHC	2013-07-19 08:30	george	XI*	Locked	Popkhadze, george	2017-01-26 19:42
TBI_RVDP036ZHC	2013-07-19 08:30	george	-	Locked	Popkhadze, george	2017-01-26 19:41
TBI_RVDP036ZHC	2013-07-19 08:30	george	UATJL*	Locked	Popkhadze, george	2017-01-26 19:40
TBI_RVDP036ZHC	2013-07-19 08:30	george	Exam_EE	Locked	Popkhadze, george	2017-01-26 19:40
TBI_RVGH486TL7	2016-10-30 00:00	Baseline Visit	OV form	In Progress	Vovk, Olga	
TBI_RVDP036ZHC	2016-10-30 00:00	other	Build8640	In Progress	Vovk, Olga	
TBI_RVDP036ZHC	2016-06-24 17:29	Baseline Visit	Build8640	In Progress	Admin, Portal	
TBI_RVDP036ZHC	2016-06-24 16:47	Baseline Visit	June24th2016	Locked	Admin, Portal	2016-06-24 16:49
TBI_RVDP036ZHC	2016-04-28 13:20	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
TBIDEMOD8725JVA	2016-04-28 12:59	Baseline Visit	Glasgow Coma Scale	Completed	Subject	
TBI_RVGH486TL7	2014-01-23 09:00	other	Multi Select Test 2	In Progress	McAuliffe, Matthew	
TBI_RVGH486TL7	2014-06-12 10:49	Baseline Visit	Multi Select Test 2	Locked	Bigos, Thomas	2014-06-12 10:49

- Select the **Open with** Internet Explorer (default) option and Click **OK** button to launch the CSV file.



Opening exportCollections_GlasgowComaScale_2017-08-28_23.18.42.csv

You have chosen to open:

 **exportCollections_GlasgowComaScale_2017-08-28_23.18.42.csv**
 which is: Microsoft Excel Comma Separated Values File
 from: https://fitbir-demo.cit.nih.gov

What should Firefox do with this file?

☒ **Open with** Internet Explorer (default)

☐ **Save File**

☐ Do this automatically for files like this from now on.

OK **Cancel**

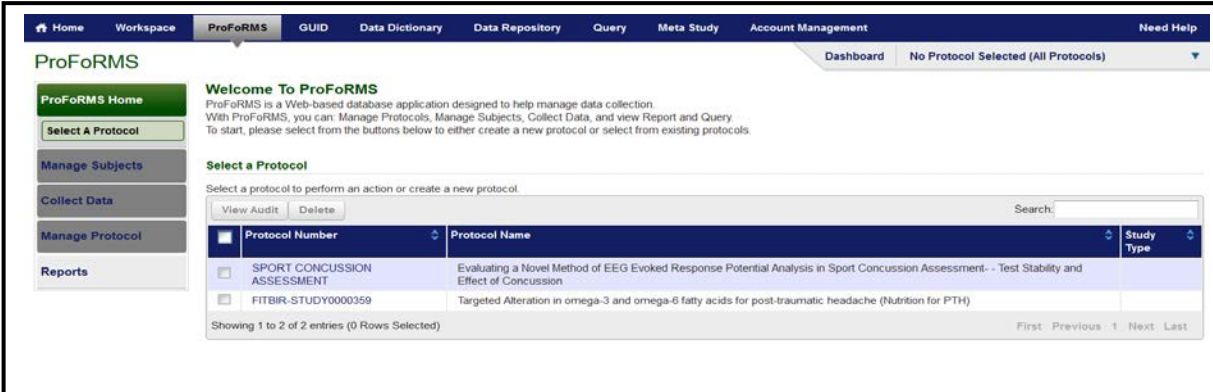
3.8 MANAGE PROTOCOL

This feature is designed to help the researchers to add and edit study information, schedule create study visits, manage visit types individual subjects across multiple studies within the system, upload subject related document.

3.8.1 Viewing Protocol Information

To view Protocol information: Perform the following actions:

1. Navigate to the **ProFoRMS** module



ProFoRMS

Dashboard | No Protocol Selected (All Protocols)

Welcome To ProFoRMS

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Select a Protocol

Select a protocol to perform an action or create a new protocol.

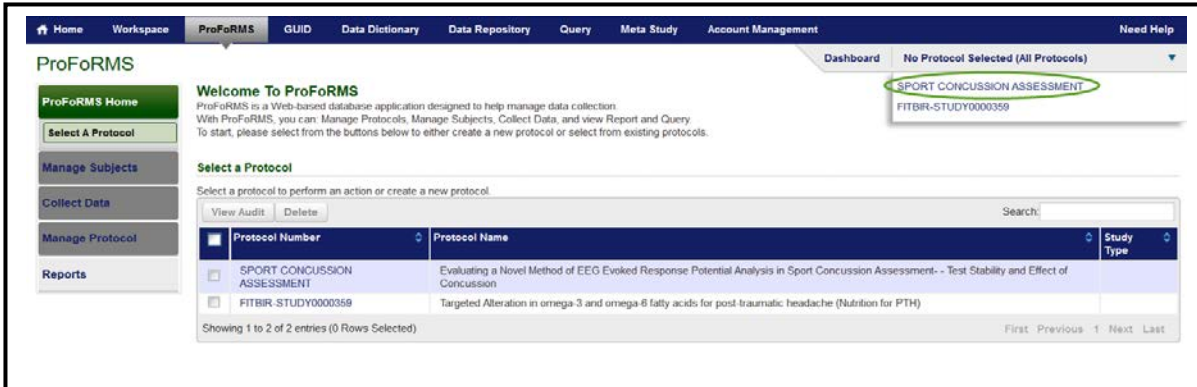
View Audit | Delete

Search:

Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment- Test Stability and Effect of Concussion	
<input type="checkbox"/> FITBR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) | First Previous 1 Next Last

2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



ProFoRMS

Dashboard | No Protocol Selected (All Protocols)

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol.

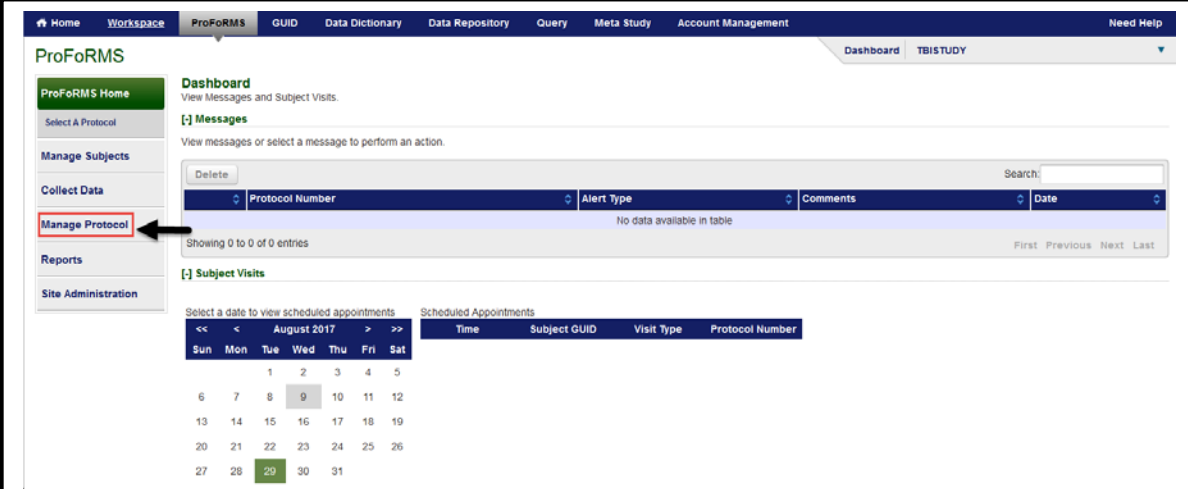
View Audit | Delete

Search:

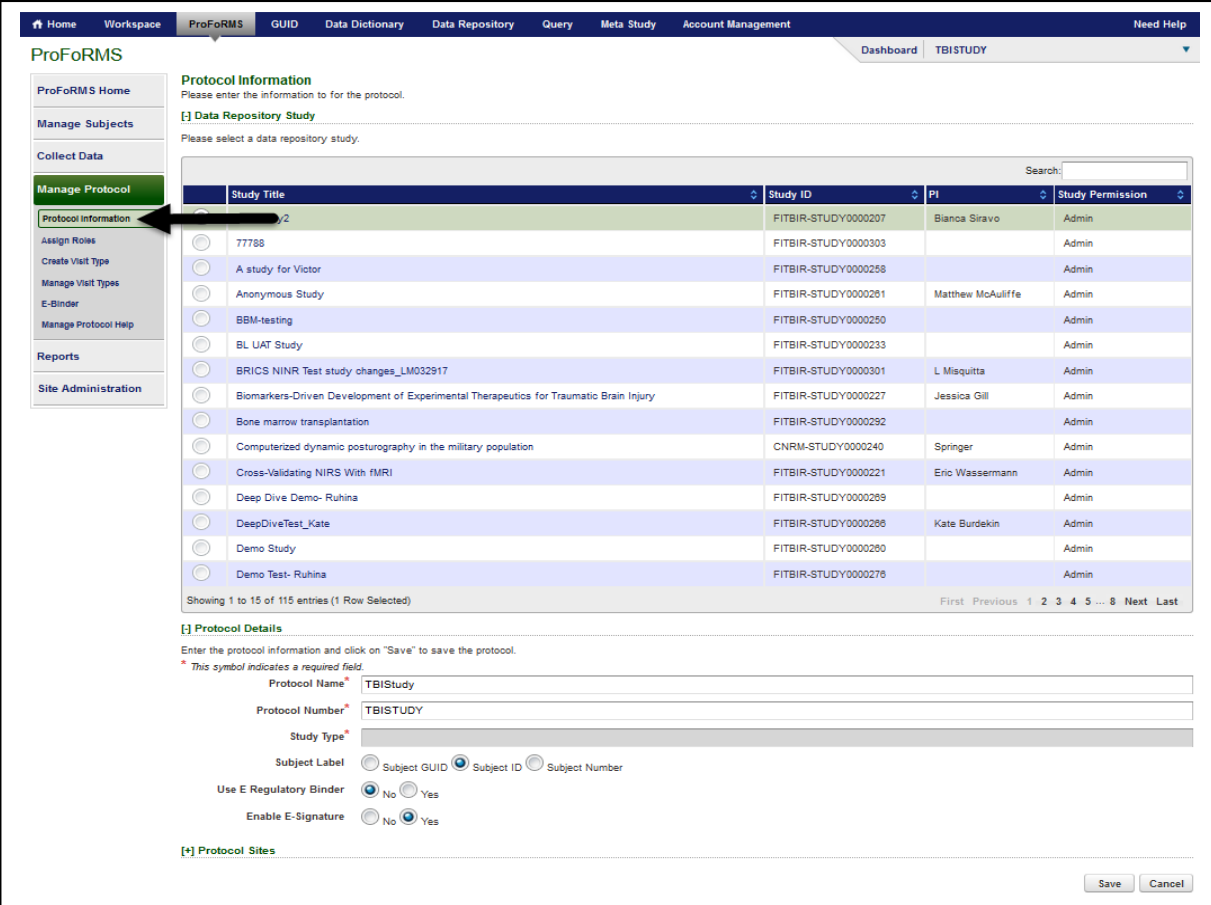
Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment- Test Stability and Effect of Concussion	
<input type="checkbox"/> FITBR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) | First Previous 1 Next Last

3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



4. Click the **Protocol Information** on the left-side tool bar. The Study Information page appears.



5. Click the **Study Title** to open the Protocol.

[Home](#)
[Workspace](#)
[ProFoRMS](#)
[GUID](#)
[Data Dictionary](#)
[Data Repository](#)
[Query](#)
[Meta Study](#)
[Account Management](#)
[Need Help](#)

Dashboard
TBI STUDY

ProFoRMS Home
Manage Subjects
Collect Data
Manage Protocol
Protocol information
Assign Roles
Create Visit Type
Manage Visit Types
E-Binder
Manage Protocol Help
Reports
Site Administration

Protocol Information

Please enter the information for the protocol.

[+] **Data Repository Study**

Please select a data repository study.

	Study Title	Study ID	PI	Study Permission
<input type="radio"/>	TestStudy2	FITBIR-STUDY0000207	Bianca Siravo	Admin
<input type="radio"/>	77788	FITBIR-STUDY0000303		Admin
<input type="radio"/>	A study for Victor	FITBIR-STUDY0000258		Admin
<input type="radio"/>	Anonymous Study	FITBIR-STUDY0000281	Matthew McAuliffe	Admin
<input type="radio"/>	BBM-testing	FITBIR-STUDY0000250		Admin
<input type="radio"/>	BL UAT Study	FITBIR-STUDY0000233		Admin
<input type="radio"/>	BRICS NINR Test study changes_LM032917	FITBIR-STUDY0000301	L Misquitta	Admin
<input type="radio"/>	Biomarkers-Driven Development of Experimental Therapeutics for Traumatic Brain Injury	FITBIR-STUDY0000227	Jessica Gill	Admin
<input type="radio"/>	Bone marrow transplantation	FITBIR-STUDY0000292		Admin
<input type="radio"/>	Computerized dynamic posturography in the military population	CNRM-STUDY0000240	Springer	Admin
<input type="radio"/>	Cross-Validating NIRS With fMRI	FITBIR-STUDY0000221	Eric Wassermann	Admin
<input type="radio"/>	Deep Dive Demo- Ruhina	FITBIR-STUDY0000289		Admin
<input type="radio"/>	DeepDiveTest_Kate	FITBIR-STUDY0000296	Kate Burdekin	Admin
<input type="radio"/>	Demo Study	FITBIR-STUDY0000280		Admin
<input type="radio"/>	Demo Test- Ruhina	FITBIR-STUDY0000278		Admin

Showing 1 to 15 of 115 entries (1 Row Selected)

[+] Protocol Details

Enter the protocol information and click on "Save" to save the protocol.

* This symbol indicates a required field.

Protocol Name* TBISTudy

Protocol Number* TBISTUDY

Study Type*

Subject Label ☐ Subject GUID ☒ Subject ID ☐ Subject Number

Use E Regulatory Binder ☒ No ☐ Yes

Enable E-Signature ☐ No ☒ Yes

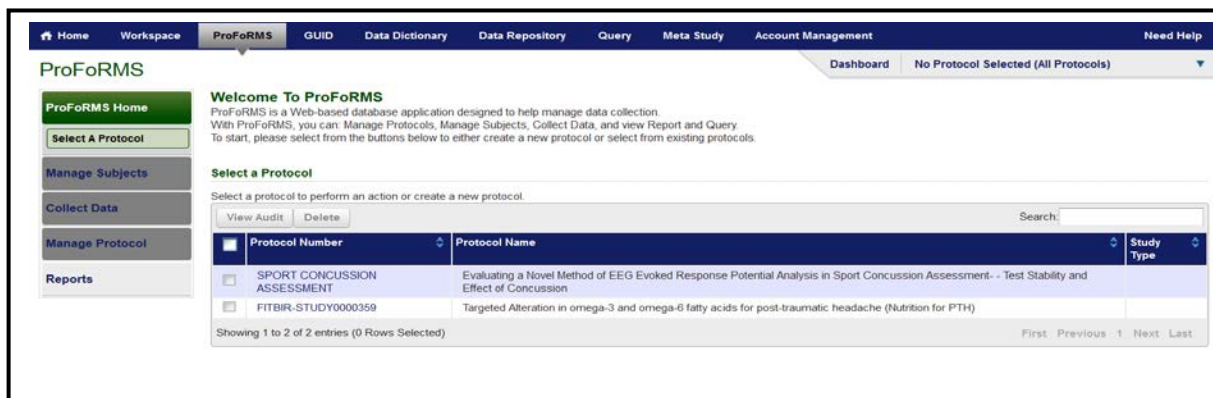
[+] Protocol Sites

Save Cancel

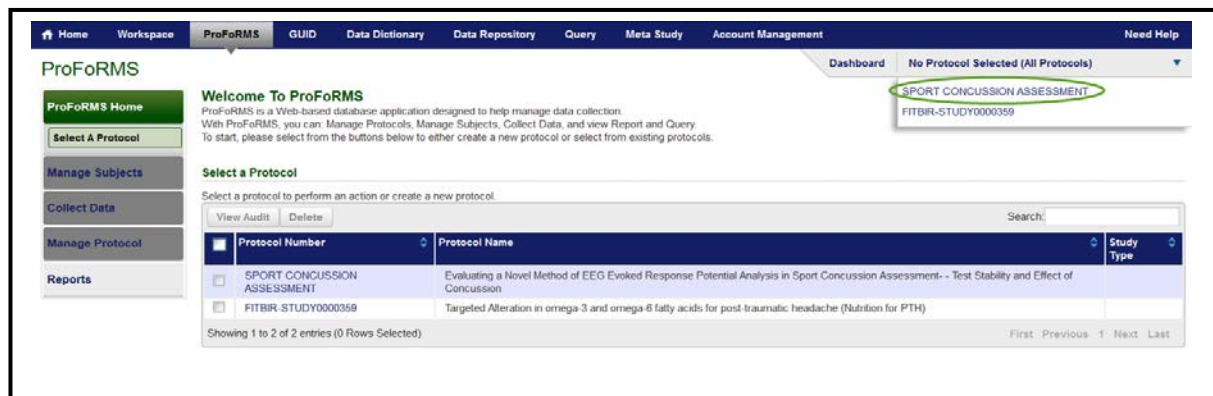
3.8.2 Assign Roles

To assign roles within a study: Perform the following actions:

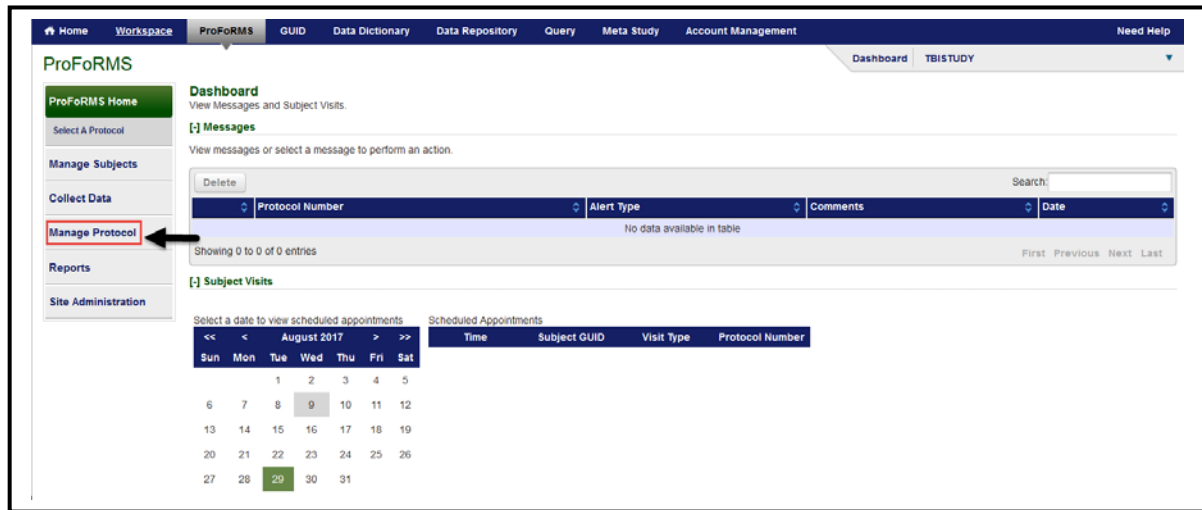
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.

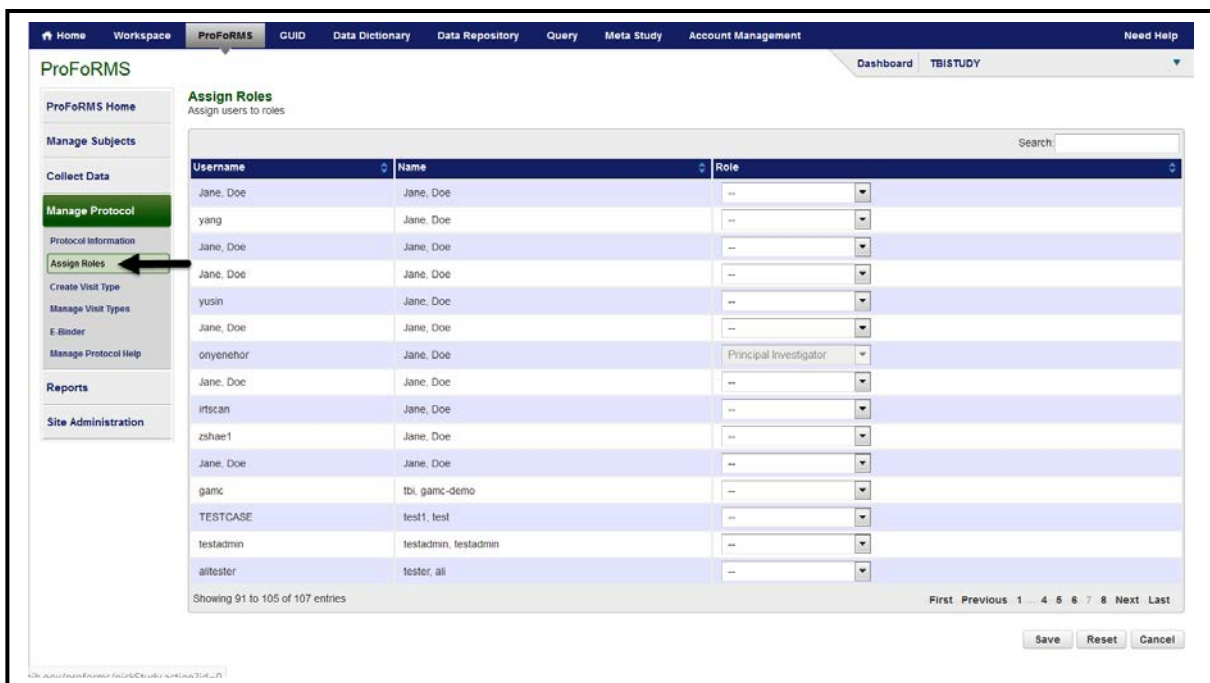


3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



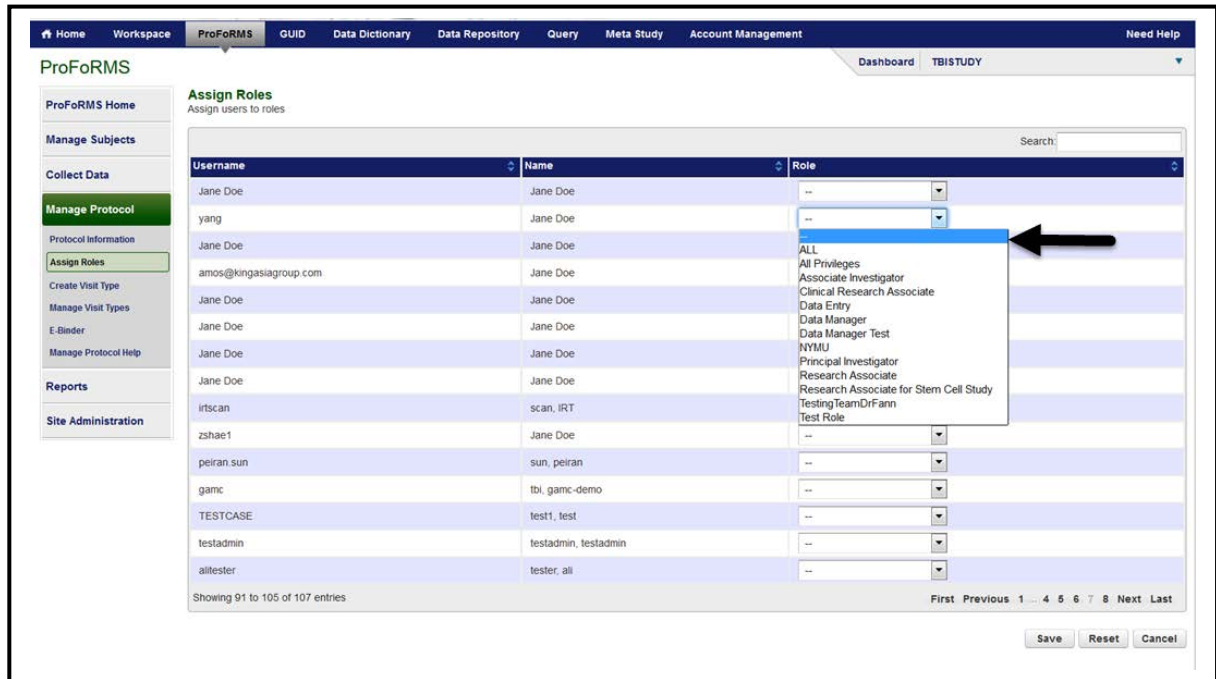
The screenshot shows the ProFoRMS Dashboard. The left sidebar contains the following menu items: ProFoRMS Home, Select A Protocol, Manage Subjects, Collect Data, **Manage Protocol** (highlighted with a red box and an arrow), Reports, and Site Administration. The main content area is titled 'Dashboard' and includes a 'Messages' section with a search bar and a table with columns: Protocol Number, Alert Type, Comments, and Date. Below this is a 'Subject Visits' section with a calendar view for August 2017 and a table with columns: Time, Subject GUID, Visit Type, and Protocol Number.

4. Click the **Assign Roles** button on the left-side tool bar. The Assign Roles page appears.



The screenshot shows the ProFoRMS Assign Roles page. The left sidebar contains the following menu items: ProFoRMS Home, Manage Subjects, Collect Data, **Assign Roles** (highlighted with a green box and an arrow), Protocol Information, Create Visit Type, Manage Visit Types, E-Binder, Manage Protocol Help, Reports, and Site Administration. The main content area is titled 'Assign Roles' and includes a search bar and a table with columns: Username, Name, and Role. The table lists various users and their roles, including Jane, Doe, yang, Jane, Doe, yusun, Jane, Doe, onyenehor, Jane, Doe, irtscan, Jane, Doe, zshae1, Jane, Doe, gamec, TESTCASE, testadmin, and alitester. The bottom of the page shows 'Showing 91 to 105 of 107 entries' and navigation buttons: First, Previous, 1, 4, 5, 6, 7, 8, Next, Last, Save, Reset, and Cancel.

5. In the **Assign Roles** page, find a user from the list of users. Use the drop-down menu to select and assign roles for a user in that study. The user roles depend on the study set up and can be as follows: Principal Investigator (max privileges), Clinical Coordinator, Study QA, Data Entry, etc.



ProFoRMS
Assign users to roles

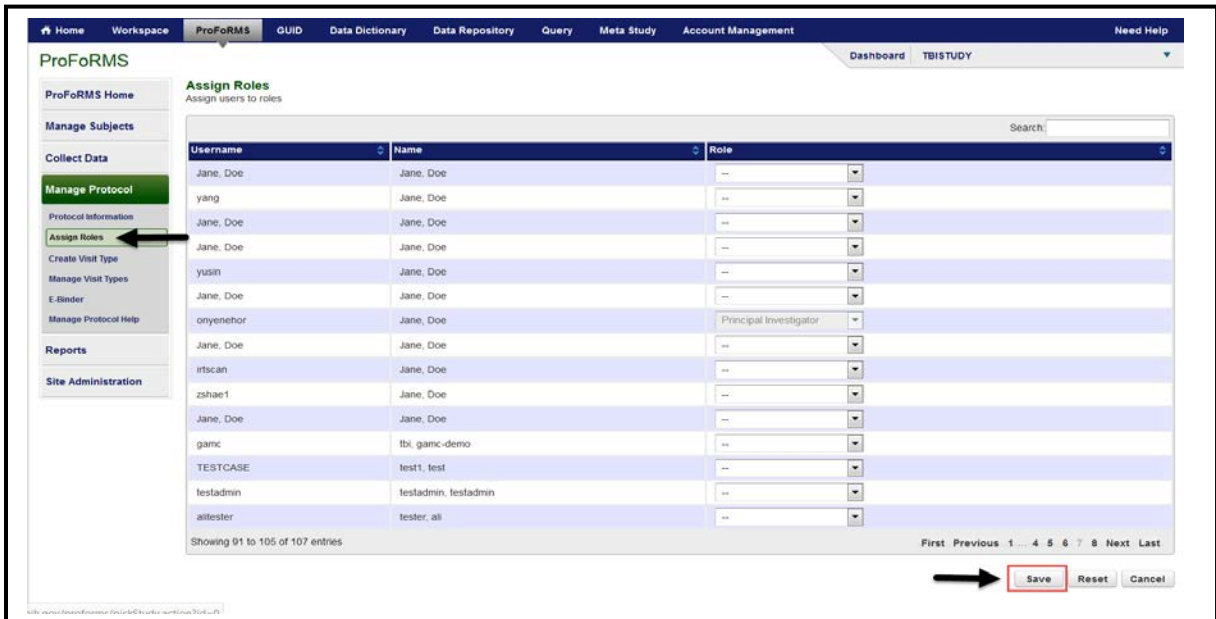
Username	Name	Role
Jane Doe	Jane Doe	...
yang	Jane Doe	...
Jane Doe	Jane Doe	ALL
amos@kingasiagroup.com	Jane Doe	...
Jane Doe	Jane Doe	...
Jane Doe	Jane Doe	...
Jane Doe	Jane Doe	...
Jane Doe	Jane Doe	...
Jane Doe	Jane Doe	...
irtscan	scan, irt	...
zshae1	Jane Doe	...
peiran.sun	sun, peiran	...
gamc	tbi, gamc-demo	...
TESTCASE	test1, test	...
testadmin	testadmin, testadmin	...
alltester	tester, all	...

Showing 91 to 105 of 107 entries

First Previous 1 ... 4 5 6 7 8 Next Last

Save Reset Cancel

6. Click the **Save** button. The new user role(s) appear in the protocol set up.



ProFoRMS
Assign users to roles

Username	Name	Role
Jane, Doe	Jane, Doe	...
yang	Jane, Doe	...
Jane, Doe	Jane, Doe	...
Jane, Doe	Jane, Doe	...
yusin	Jane, Doe	...
Jane, Doe	Jane, Doe	...
onyenehor	Jane, Doe	Principal Investigator
Jane, Doe	Jane, Doe	...
irtscan	Jane, Doe	...
zshae1	Jane, Doe	...
Jane, Doe	Jane, Doe	...
gamc	tbi, gamc-demo	...
TESTCASE	test1, test	...
testadmin	testadmin, testadmin	...
alltester	tester, all	...

Showing 91 to 105 of 107 entries

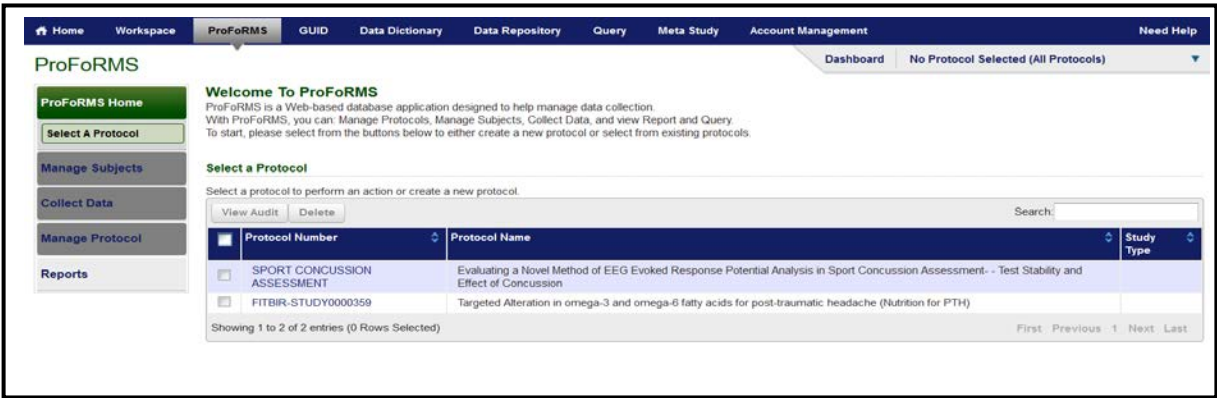
First Previous 1 ... 4 5 6 7 8 Next Last

Save Reset Cancel

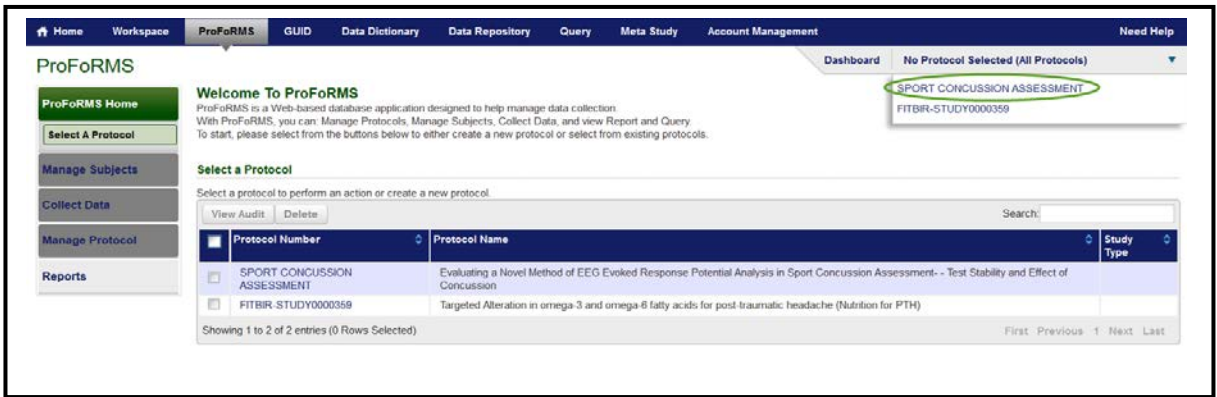
3.8.1 Manage Visit Types

To manage visit types: Perform the following actions:

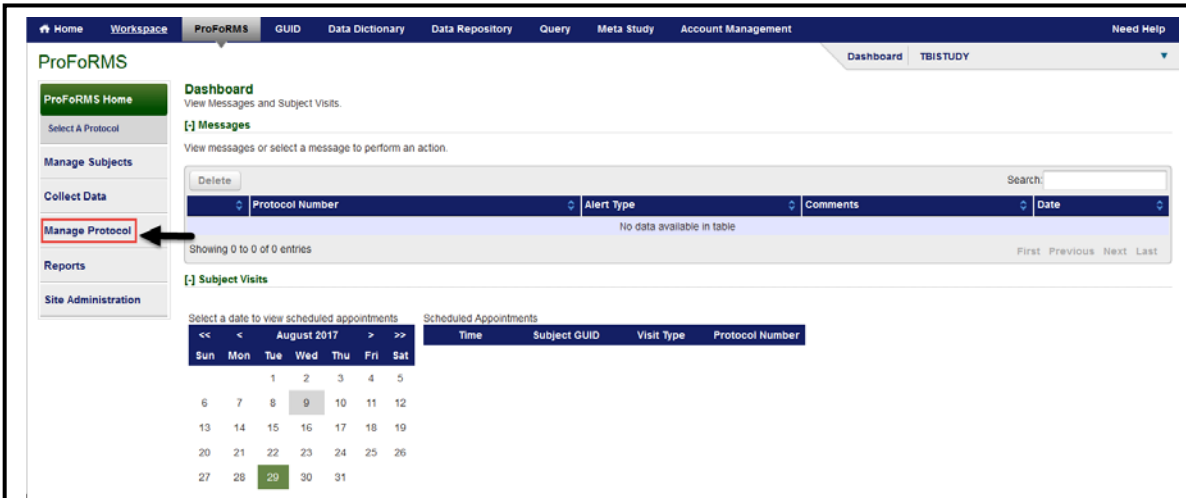
- 1. Navigate to the **ProFoRMS** module



- 2. Select a **Protocol** by using the drop-down menu located on the top right-hand.

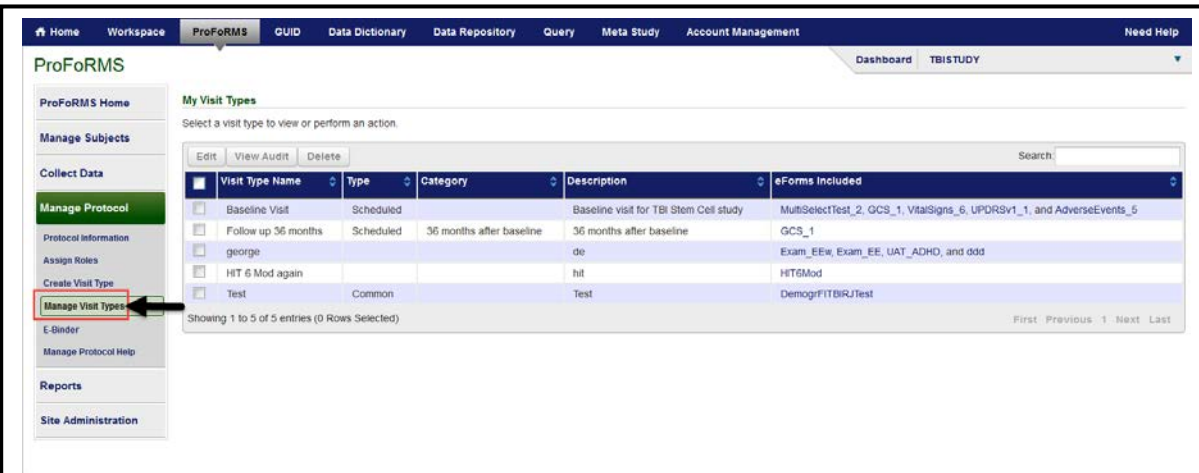


3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



The screenshot shows the ProFoRMS Dashboard. On the left sidebar, the 'Manage Protocol' button is highlighted with a red box and an arrow. The main content area displays the 'Dashboard' with sections for 'Messages' and 'Subject Visits'.

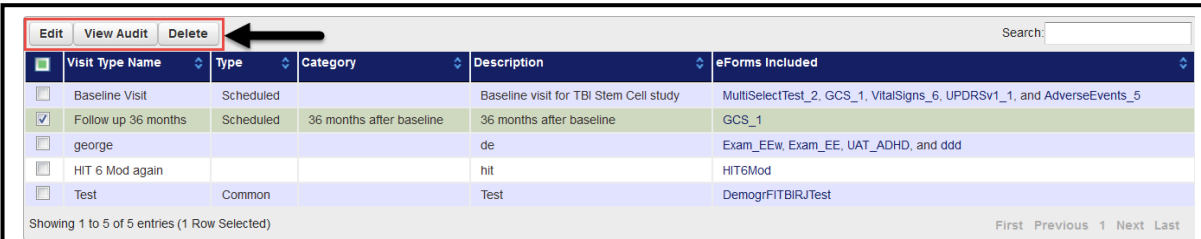
4. Click the **Manage Visit Types** button on the left-side tool bar. The My Visit Types page appears.



The screenshot shows the 'My Visit Types' page. On the left sidebar, the 'Manage Visit Types' button is highlighted with a red box and an arrow. The main content area displays a table of visit types.

Visit Type Name	Type	Category	Description	eForms Included
Baseline Visit	Scheduled		Baseline visit for TBI Stem Cell study	MultiSelectTest_2, GCS_1, VitalSigns_6, UPDRSv1_1, and AdverseEvents_5
Follow up 36 months	Scheduled	36 months after baseline	36 months after baseline	GCS_1
george			de	Exam_EE, Exam_EE, UAT_ADHD, and ddd
HIT 6 Mod again			hit	HIT6Mod
Test	Common		Test	DemogrFITBIRJTest

5. Select the Check-box beside the **Visit Type Name** to perform an action: **Edit**, **View Audit** and **Delete** functions.



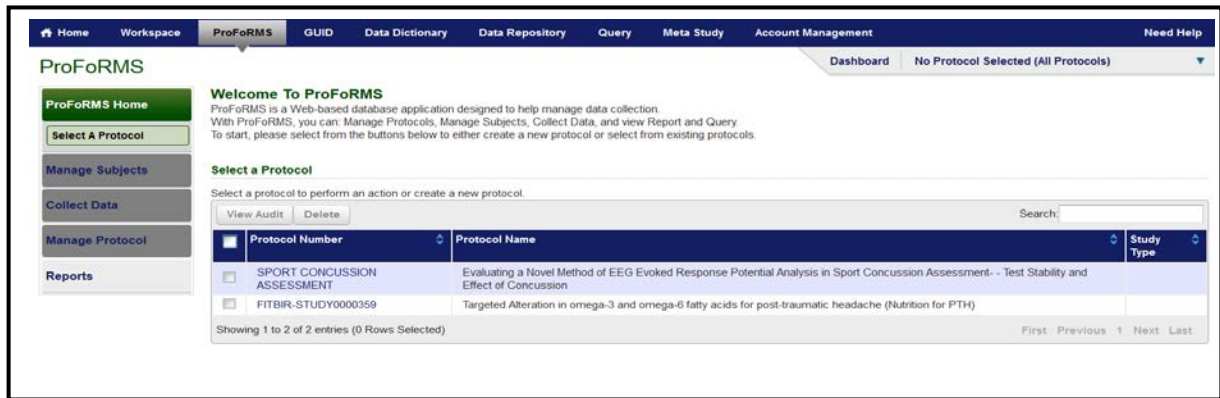
The screenshot shows the 'My Visit Types' page with the 'Edit', 'View Audit', and 'Delete' buttons highlighted in red. The 'Follow up 36 months' row is selected.

Visit Type Name	Type	Category	Description	eForms Included
<input type="checkbox"/> Baseline Visit	Scheduled		Baseline visit for TBI Stem Cell study	MultiSelectTest_2, GCS_1, VitalSigns_6, UPDRSv1_1, and AdverseEvents_5
<input checked="" type="checkbox"/> Follow up 36 months	Scheduled	36 months after baseline	36 months after baseline	GCS_1
<input type="checkbox"/> george			de	Exam_EE, Exam_EE, UAT_ADHD, and ddd
<input type="checkbox"/> HIT 6 Mod again			hit	HIT6Mod
<input type="checkbox"/> Test	Common		Test	DemogrFITBIRJTest

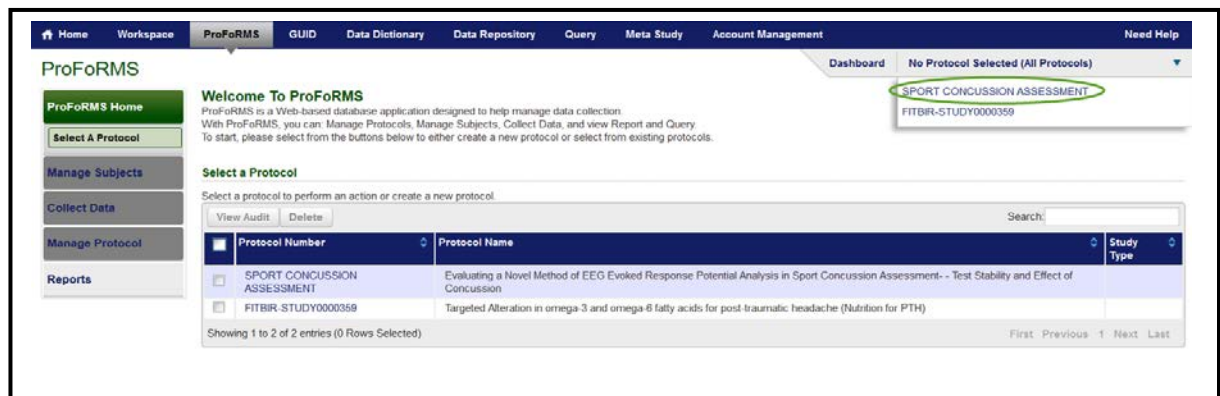
3.8.2 Create Visit Types

To create visit types: Perform the following actions:

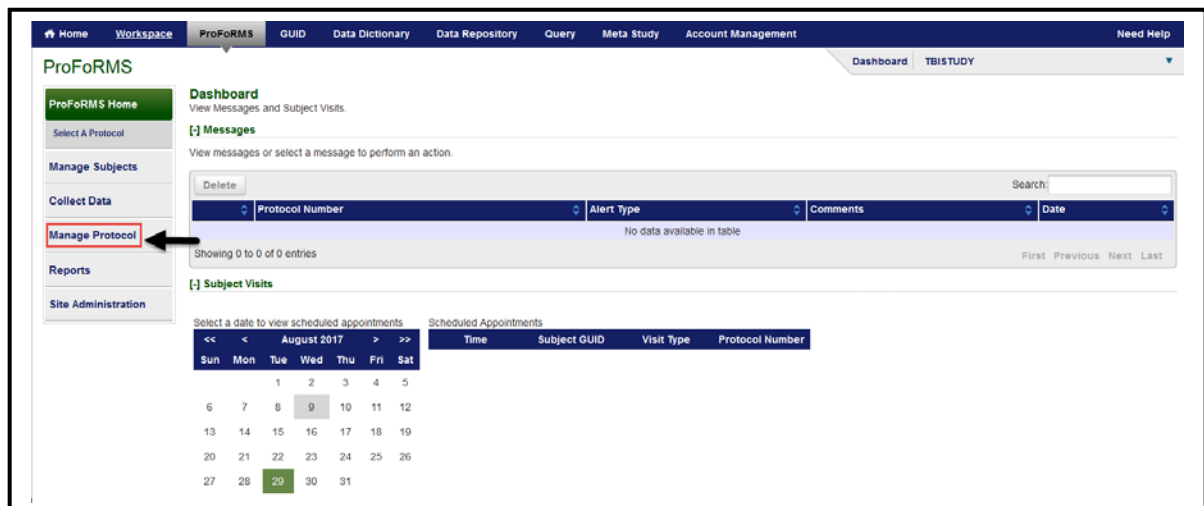
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



- Click the **Create Visit Type** button on the left-side tool bar. The Create Visit Type page appears.

ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

ProFoRMS Home

Manage Subjects

Collect Data

Manage Protocol

Protocol Information

Assign Roles

Create Visit Type

Manage Visit Types

E-Binder

Manage Protocol Help

Reports

Site Administration

Create Visit Type

Create a new visit type, select a visit type to view or perform an action.

* This symbol indicates a required field

Visit Type Name *

Visit Type Please select Type

Category

Description *

Self Reporting eForms * Available 15 days before the scheduled visit until 15 days after the scheduled visit.

Associate Published eForms:

eForm Name	eForm Short Name	Description	Required?	Self Reporting?
adut	UAT_ADHDew	The ASRS is a self-report scale for adults to help...	Required Optional	Yes No
Adverse Events	AdverseEvents_16		Required Optional	Yes No
BILLY	BILLY	Dolorumque impedit, eos, velit facit officia off...	Required Optional	Yes No
Demographics Standard FITBIR	DemogrFITBIRJTest	Demographics standard form created by FITBIR Ops	Required Optional	Yes No
Eligibility Checklist - IK1	EligibilityChecklistIK1	Eligibility Checklist - sub-study IK1	Required Optional	Yes No
Encounter Form - IK1	EncounterFormIK1	Encounter Form sub-study IK1	Required Optional	Yes No
Exam_EE	Exam_EE	Testing creating a form. Added text	Required Optional	Yes No
Exam_EE33	Exam_EE33	Testing creating a form. Added text	Required Optional	Yes No

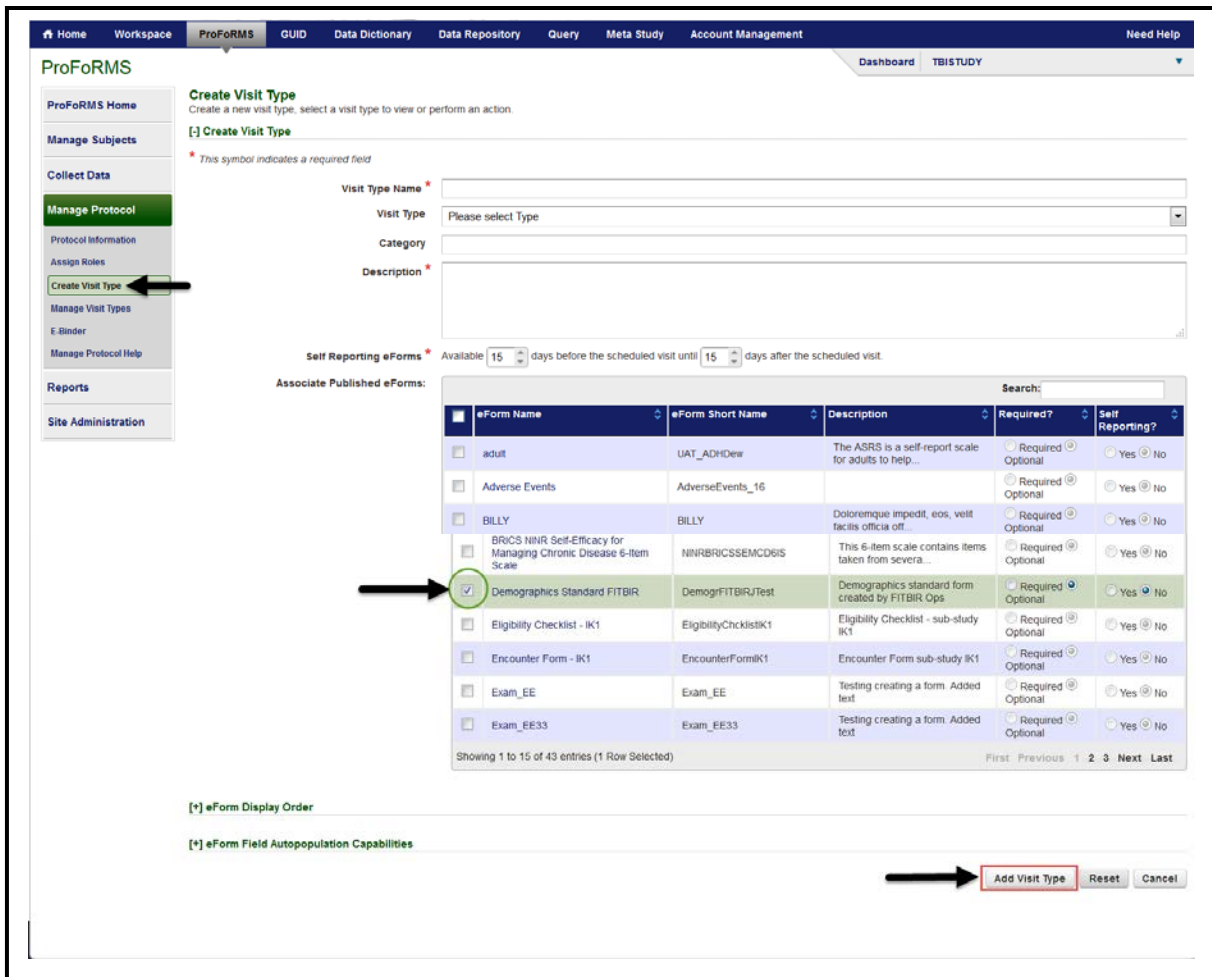
Showing 1 to 15 of 43 entries (0 Rows Selected) First Previous 1 2 3 Next Last

[*] eForm Display Order

[*] eForm Field Autopopulation Capabilities

Add Visit Type Reset Cancel

5. Create a new visit type by entering the **Visit Type Name**, **Visit Type**, and a **Short Description**. Associate published eForms to your visit by selecting the **check-box** beside the **eForm Name**. Select the check-boxes beside the eForm(s) to associate published eForms. Then, use the up and down button to change the order under: “ **(-) eForm Display Order**” The list only contains the eForms that are selected within the visit type.
Finally, the fields within the eForms associated with this visit type have the ability to be autopopulated during data collection period after they are autopopulated. Select the fields to enable autopopulation within this visit type under “**(+) eForm Autopopulation capabilities**”. You may have to provide additional information when scheduling a visit for a particular subject. Click the **Add Visit Type** button.



ProFoRMS

Create Visit Type
Create a new visit type, select a visit type to view or perform an action.

[-] Create Visit Type

* This symbol indicates a required field

Visit Type Name *

Visit Type Please select Type

Category

Description *

Self Reporting eForms Available 15 days before the scheduled visit until 15 days after the scheduled visit.

Associate Published eForms:

eForm Name	eForm Short Name	Description	Required?	Self Reporting?
adult	UAT_ADHDew	The ASRS is a self-report scale for adults to help...	Required Optional	Yes No
Adverse Events	AdverseEvents_16		Required Optional	Yes No
BILLY	BILLY	Doitremque impedit, eos, veit facis officia off...	Required Optional	Yes No
BRICS NINR Self-Efficacy for Managing Chronic Disease 6-Item Scale	NINRBRICSSEMCDSIS	This 6-item scale contains items taken from severa...	Required Optional	Yes No
<input checked="" type="checkbox"/> Demographics Standard FITBIR	DemogrFITBIRJTest	Demographics standard form created by FITBIR Ops	Required Optional	Yes No
Eligibility Checklist - IK1	EligibilityChcklistIK1	Eligibility Checklist - sub-study IK1	Required Optional	Yes No
Encounter Form - IK1	EncounterFormIK1	Encounter Form sub-study IK1	Required Optional	Yes No
Exam_EE	Exam_EE	Testing creating a form. Added text	Required Optional	Yes No
Exam_EE33	Exam_EE33	Testing creating a form. Added text	Required Optional	Yes No

Showing 1 to 15 of 43 entries (1 Row Selected)

First Previous 1 2 3 Next Last

[+] eForm Display Order

[+] eForm Field Autopopulation Capabilities

Add Visit Type Reset Cancel

6. The new visit type(s) appears in the **My Visit Type** page.

ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard TBISTUDY

The "Test" visit type has been added successfully.

My Visit Types

Select a visit type to view or perform an action.

Edit View Audit Delete Search:

<input type="checkbox"/>	Visit Type Name	Type	Category	Description	eForms Included
<input type="checkbox"/>	Baseline Visit	Scheduled		Baseline visit for TBI Stem Cell study	MultiSelectTest_2, GCS_1, VitalSigns_6, UPDRSv1_1, and AdverseEvents_5
<input type="checkbox"/>	Follow up 36 months	Scheduled	36 months after baseline	36 months after baseline	GCS_1
<input type="checkbox"/>	george			de	Exam_EEw, Exam_EE, UAT_ADHD, and ddd
<input type="checkbox"/>	HIT 6 Mod again			hit	HIT6Mod
<input type="checkbox"/>	Test	Common		Test	DemogriPITBIRUtest

Showing 1 to 5 of 5 entries (0 Rows Selected) First Previous 1 Next Last

ProFoRMS Home

Manage Subjects

Collect Data

Manage Protocol

Protocol Information

Assign Roles

Create Visit Type

Manage Visit Types

E-Binder

Manage Protocol Help

Reports

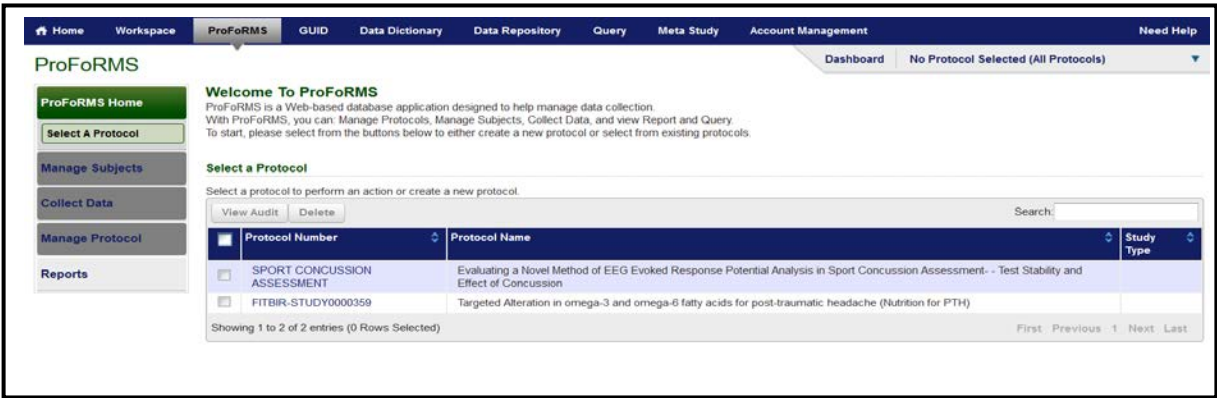
Site Administration

3.8.3 Patient Self Reporting (PSR)

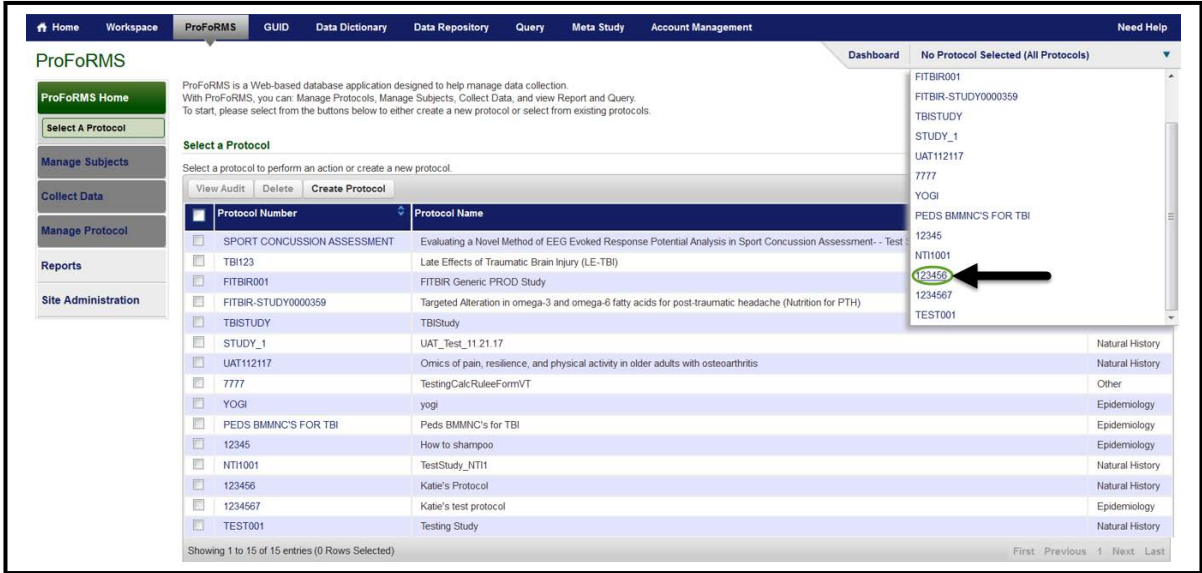
Patient Self-Reporting is an Admin-enabled function. You must have an administrative privilege in order to use this feature. Ensure you have Administrative privileges enabled before attempting to set up patient self-reporting in ProFORMS.

To view **Performance Overview Report**: Perform the following actions:

- 1. Navigate to the **ProFoRMS** module



- 2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

123456

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Site Administration

View Messages and Subject Visits.

[-] Messages

View messages or select a message to perform an action.

Delete

Search

Protocol Number	Alert Type	Comments	Date
No data available in table			

Showing 0 to 0 of 0 entries

First Previous Next Last

[-] Subject Visits

Select a date to view scheduled appointments

Scheduled Appointments

Time	Subject GUID	Visit Type	Protocol Number																																										
<div> <div><<</div> <div><</div> <div>February 2018</div> <div>></div> <div>>></div> </div> <table> <tr> <td>Sun</td> <td>Mon</td> <td>Tue</td> <td>Wed</td> <td>Thu</td> <td>Fri</td> <td>Sat</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td>1</td> <td>2</td> <td>3</td> </tr> <tr> <td>4</td> <td>5</td> <td>6</td> <td>7</td> <td>8</td> <td>9</td> <td>10</td> </tr> <tr> <td>11</td> <td>12</td> <td>13</td> <td>14</td> <td>15</td> <td>16</td> <td>17</td> </tr> <tr> <td>18</td> <td>19</td> <td>20</td> <td>21</td> <td>22</td> <td>23</td> <td>24</td> </tr> <tr> <td>25</td> <td>26</td> <td>27</td> <td>28</td> <td></td> <td></td> <td></td> </tr> </table>				Sun	Mon	Tue	Wed	Thu	Fri	Sat					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28			
Sun	Mon	Tue	Wed	Thu	Fri	Sat																																							
				1	2	3																																							
4	5	6	7	8	9	10																																							
11	12	13	14	15	16	17																																							
18	19	20	21	22	23	24																																							
25	26	27	28																																										

4. Click the **Manage Visit Types** button on the left-side tool bar. The **My Visit Types** page appears.

Home

Workspace

ProFoRMS

GUID

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Need Help

Dashboard

123456

ProFoRMS Home

Manage Subjects

Collect Data

Manage Protocol

Protocol Information

Assign Roles

Create Visit Type

Manage Visit Types

E-Binder

Manage Protocol Help

Reports

Site Administration

Please enter the information to for the protocol.

[-] Data Repository Study

Please select a data repository study.

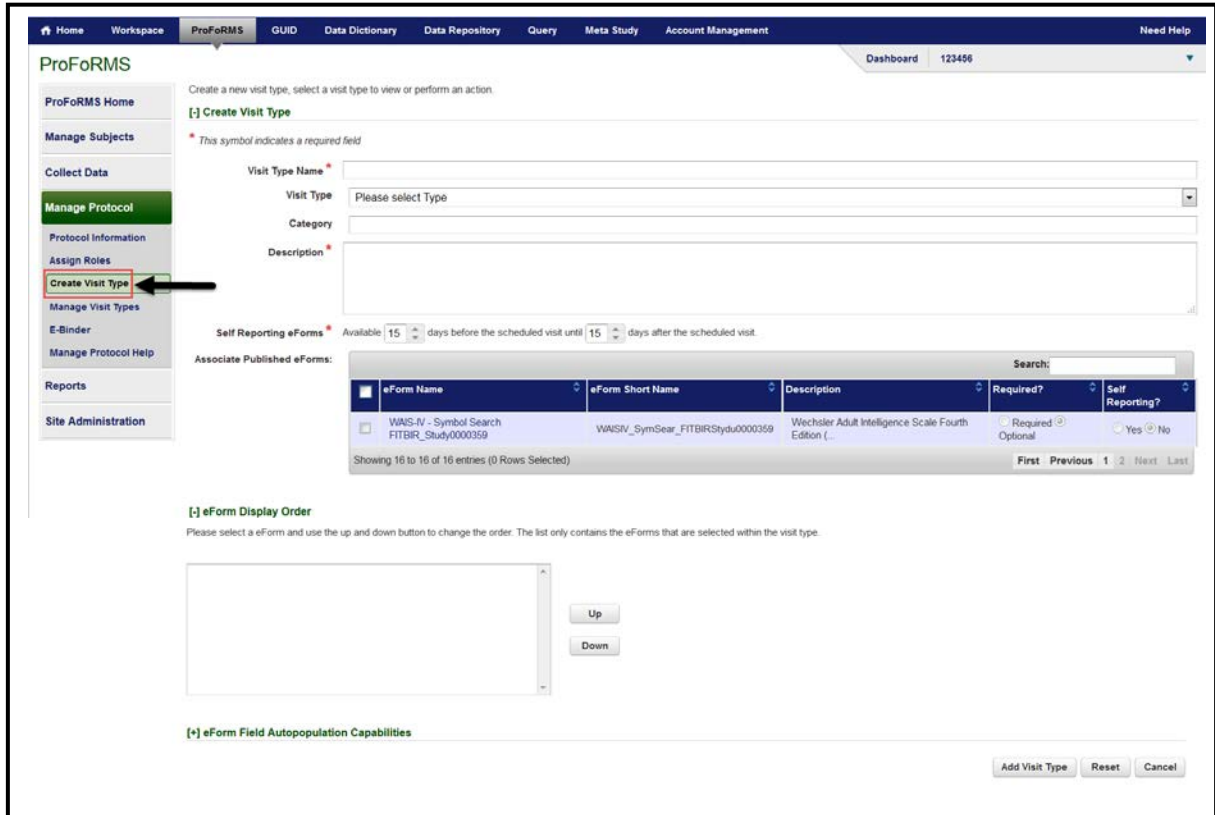
Search

Study Title	Study ID	PI	Study Permission
<input type="checkbox"/> EYE MOVEMENT DYNAMICS: A RAPID OBJECTIVE INVOLUNTARY MEASURE OF CONCUSSION/TBI	FITBR-STUDY0000261	Nicholas Port	Admin
<input type="checkbox"/> Early Recognition of Chronic Traumatic Encephalopathy Through FDDNP PET Imaging	FITBR-STUDY0000270	Charles Bernick	Admin
<input type="checkbox"/> Effect of Aerobic Exercise Training on Cardiorespiratory Function in Patients with TBI (CNRM)	FITBR-STUDY0000205	Leighton Chan	Admin
<input type="checkbox"/> Effect of Reward on Learning in Motor Cortex	FITBR-STUDY0000212	Eric Wassermann	Admin
<input type="checkbox"/> Effects of Erythropoietin on Cerebral Vascular Dysfunction and Anemia in Traumatic Brain Injury	FITBR-STUDY0000249	Claudia Robertson	Admin
<input type="checkbox"/> Effects of Rapid-Resisted Exercise and Bright Light Therapy on Ambulatory Adults With Traumatic Brain Injury	FITBR-STUDY0000204	Diane Damiano	Admin
<input type="checkbox"/> Effects of Rapid-Resisted Exercise on Ambulatory Adults with Traumatic Brain Injury (CNRM)	FITBR-STUDY0000271	Diane Damiano	Admin
<input type="checkbox"/> Effects of Traumatic Brain Injury and Post-Traumatic Stress Disorder and Alzheimer's Disease on Brain Tau in Vietnam Veterans using ADNI	FITBR-STUDY0000352	Michael Weiner	Admin
<input type="checkbox"/> Enhancing the Detection and Management of mTBI in Military Personnel	FITBR-STUDY0000317		Admin
<input type="checkbox"/> Enzymagym	FITBR-STUDY0000224	Barry E. Kosofsky	Admin
<input type="checkbox"/> Evaluation and Diagnosis of Potential Research Subjects With Traumatic Brain Injury	FITBR-STUDY0000206	Lawrence Latour	Admin
<input type="checkbox"/> Evaluation of Military Service and Family Members for Post Concussive and Posttraumatic Stress Symptoms (CNRM)	FITBR-STUDY0000303	Michael Roy	Admin
<input type="checkbox"/> Evaluation of Outcome Measures for Patients Diagnosed with TBI	FITBR-STUDY0000203	Leighton Chan	Admin
<input type="checkbox"/> Evaluation of Spot Light: A concussion injury management app for youth	FITBR-STUDY0000269	Lara McKenzie	Admin
<input type="checkbox"/> Evaluation of the DVBIC Clinical Recommendation for Management of Headache Following Concussion	FITBR-STUDY0000355	Sidney R Hinds	Admin

Showing 61 to 75 of 178 entries (1 Row Selected)

First Previous 1 4 5 6 12 Next Last

- Click **Create Visit Type** button on the left-side tool bar. The **Create Visit Type** page appears.



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard 123456

Create a new visit type, select a visit type to view or perform an action.

[+] Create Visit Type

* This symbol indicates a required field

Visit Type Name *

Visit Type Please select Type

Category

Description *

Self Reporting eForms Available 15 days before the scheduled visit until 15 days after the scheduled visit.

Associate Published eForms:

eForm Name	eForm Short Name	Description	Required?	Self Reporting?
WANS-IV - Symbol Search FITBPR_Study0000359	WANSIV_SymSear_FITBPRStudy0000359	Wechsler Adult Intelligence Scale Fourth Edition (...)	Required Optional	Yes No

Showing 16 to 16 of 16 entries (0 Rows Selected)

[+] eForm Display Order

Please select a eForm and use the up and down button to change the order. The list only contains the eForms that are selected within the visit type.

Up

Down

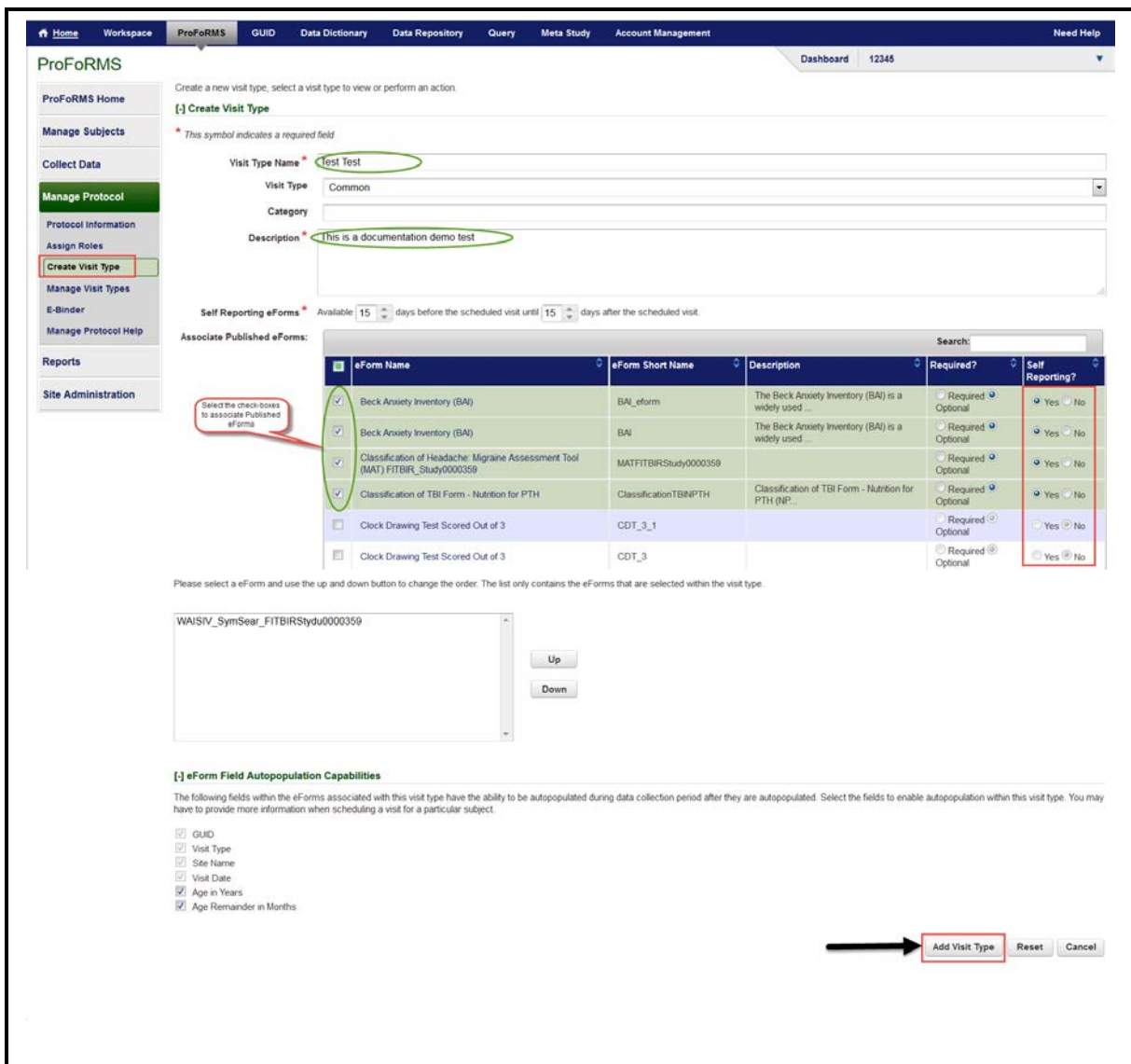
[+] eForm Field Autopopulation Capabilities

Add Visit Type Reset Cancel

6. Create a new visit type by entering the **Visit Type Name**, **Visit Type**, and a **Short Description**. Associate published eForms to your visit by selecting the **check-box** beside the **eForm Name**, Select the **Yes** under **Self Reporting**. Select the check-boxes beside the eForm(s) to associate published eForms. Under the “**Self Reporting**” column, select the check-box beside “**Yes**”.

Then, use the up and down button to change the order under: “ **(-) eForm Display Order**” The list only contains the eForms that are selected within the visit type.

Finally, the fields within the eForms associated with this visit type have the ability to be autopopulated during data collection period after they are autopopulated. Select the fields to enable autopopulation within this visit type under “**(+)eForm Autopulation capabilities**”. You may have to provide additional information when scheduling a visit for a particular subject. Click the **Add Visit Type** button.



ProFoRMS

Dashboard 12345

Create a new visit type, select a visit type to view or perform an action.

Create Visit Type

* This symbol indicates a required field

Visit Type Name *

Visit Type

Category

Description *

Self Reporting eForms * Available days before the scheduled visit until days after the scheduled visit

Associate Published eForms:

eForm Name	eForm Short Name	Description	Required?	Self Reporting?
<input checked="" type="checkbox"/> Beck Anxiety Inventory (BAI)	BAI_eform	The Beck Anxiety Inventory (BAI) is a widely used ...	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input checked="" type="radio"/> Yes <input type="radio"/> No
<input checked="" type="checkbox"/> Beck Anxiety Inventory (BAI)	BAI	The Beck Anxiety Inventory (BAI) is a widely used ...	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input checked="" type="radio"/> Yes <input type="radio"/> No
<input checked="" type="checkbox"/> Classification of Headache: Migraine Assessment Tool (MAT) FITBIR_Study000359	MATFITBIRStudy000359		<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input checked="" type="radio"/> Yes <input type="radio"/> No
<input checked="" type="checkbox"/> Classification of TBI Form - Nutrition for PTH	ClassificationTBINPTH	Classification of TBI Form - Nutrition for PTH (NP...	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input checked="" type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Clock Drawing Test Scored Out of 3	CDT_3_1		<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> Clock Drawing Test Scored Out of 3	CDT_3		<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No

Please select a eForm and use the up and down button to change the order. The list only contains the eForms that are selected within the visit type.

WASIV_SymSear_FITBIRStudy000359

(-) eForm Field Autopopulation Capabilities

The following fields within the eForms associated with this visit type have the ability to be autopopulated during data collection period after they are autopopulated. Select the fields to enable autopopulation within this visit type. You may have to provide more information when scheduling a visit for a particular subject.

☒ GUID

☒ Visit Type

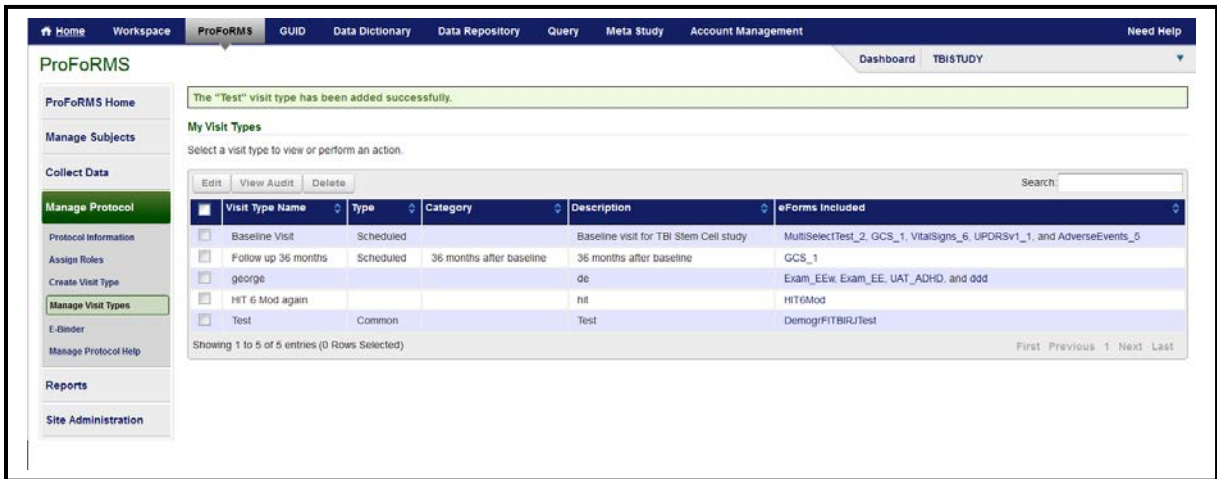
☒ Site Name

☒ Visit Date

☒ Age in Years

☒ Age Remainder in Months

7. The new visit type(s) appears in the “My Visit Type” page.



The "Test" visit type has been added successfully.

My Visit Types

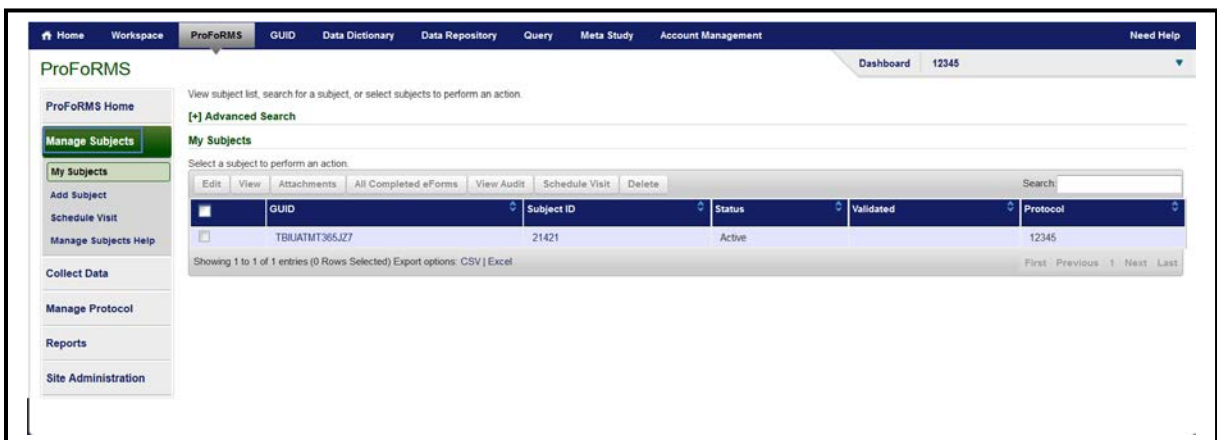
Select a visit type to view or perform an action.

Edit View Audit Delete Search:

Visit Type Name	Type	Category	Description	eForms Included
Baseline Visit	Scheduled		Baseline visit for TBI Stem Cell study	MultiSelectTest_2, GCS_1, VitalSigns_6, UPDRSv1_1, and AdverseEvents_5
Follow up 36 months	Scheduled	36 months after baseline	36 months after baseline	GCS_1
george			de	Exam_EEw, Exam_EE, UAT_ADHD, and ddd
HIT 6 Mod again			hit	HIT6Mod
Test	Common		Test	DemogPITBIRJTest

Showing 1 to 5 of 5 entries (0 Rows Selected) First Previous 1 Next Last

8. Click on **Manage Subjects** button on the left-side tool bar.



View subject list, search for a subject, or select subjects to perform an action.

[+] Advanced Search

My Subjects

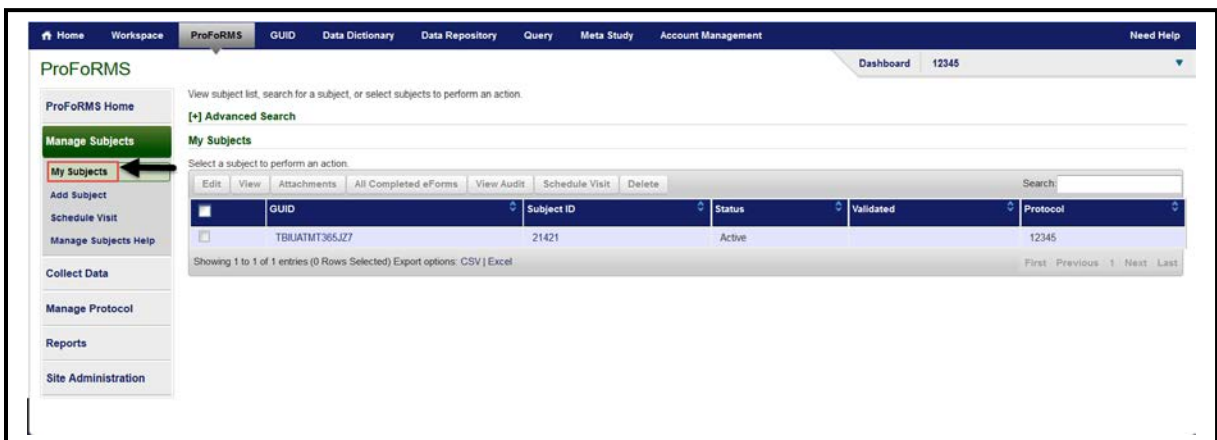
Select a subject to perform an action.

Edit View Attachments All Completed eForms View Audit Schedule Visit Delete Search:

GUID	Subject ID	Status	Validated	Protocol
TBIJATMT365.IZ7	21421	Active		12345

Showing 1 to 1 of 1 entries (0 Rows Selected) Export options: CSV | Excel First Previous 1 Next Last

9. Click on **My Subjects** on the left-side tool bar.



View subject list, search for a subject, or select subjects to perform an action.

[+] Advanced Search

My Subjects

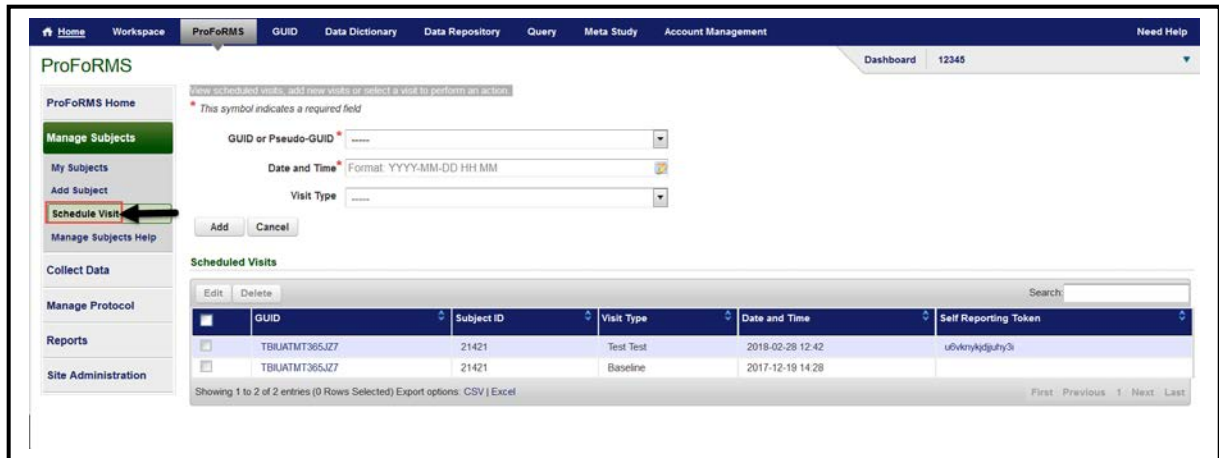
Select a subject to perform an action.

Edit View Attachments All Completed eForms View Audit Schedule Visit Delete Search:

GUID	Subject ID	Status	Validated	Protocol
TBIJATMT365.IZ7	21421	Active		12345

Showing 1 to 1 of 1 entries (0 Rows Selected) Export options: CSV | Excel First Previous 1 Next Last

10. Click the **Schedule Visit** button on the left-side tool bar.



View scheduled visits, add new visits or select a visit to perform an action.
 * This symbol indicates a required field

GUID or Pseudo-GUID *

Date and Time * Format: YYYY-MM-DD HH MM


Visit Type

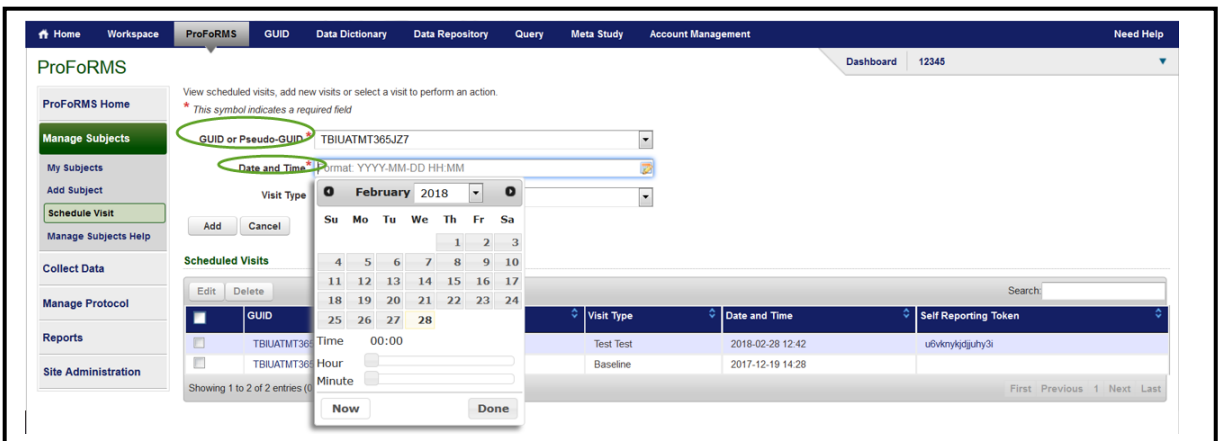
Add Cancel

Scheduled Visits

GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
TBIUATMT365JZ7	21421	Test Test	2018-02-28 12:42	u6vknypkdjy3i
TBIUATMT365JZ7	21421	Baseline	2017-12-19 14:28	

Showing 1 to 2 of 2 entries (0 Rows Selected) Export options: CSV | Excel

11. Add new visit or select a visit from the drop-down menu. * This symbol indicates a required field. Select the desired visit date by clicking on the calendar icon .



View scheduled visits, add new visits or select a visit to perform an action.
 * This symbol indicates a required field

GUID or Pseudo-GUID *

Date and Time * Format: YYYY-MM-DD HH MM

Visit Type

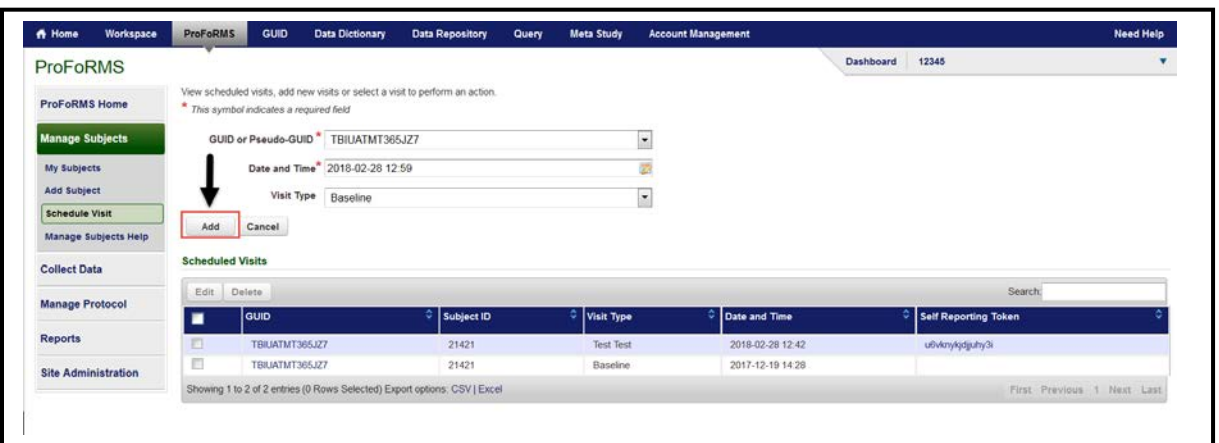
Add Cancel

Scheduled Visits

GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
TBIUATMT365JZ7	21421	Test Test	2018-02-28 12:42	u6vknypkdjy3i
TBIUATMT365JZ7	21421	Baseline	2017-12-19 14:28	

Showing 1 to 2 of 2 entries (0 Rows Selected) Export options: CSV | Excel

12. Click the **Add** button.



View scheduled visits, add new visits or select a visit to perform an action.
 * This symbol indicates a required field

GUID or Pseudo-GUID *

Date and Time * Format: YYYY-MM-DD HH MM

Visit Type

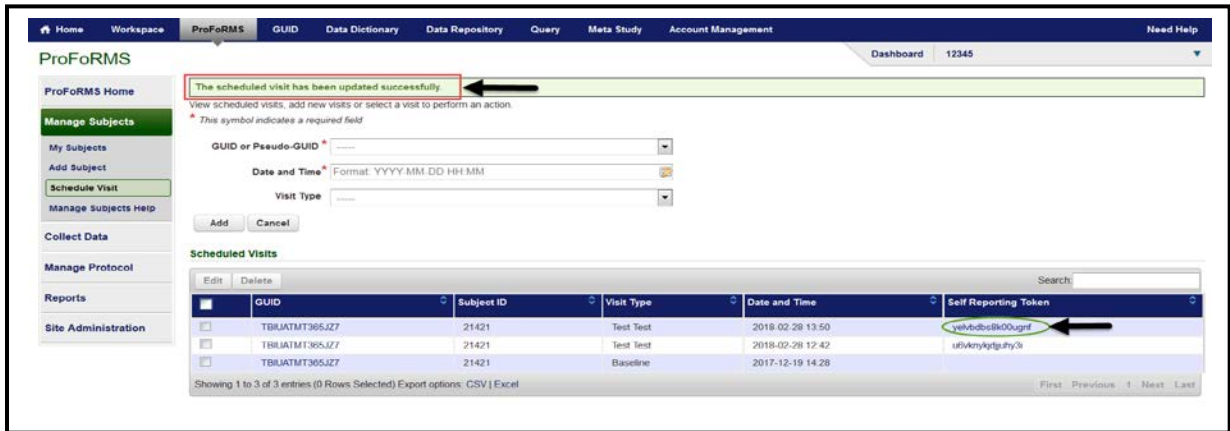
Add Cancel

Scheduled Visits

GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
TBIUATMT365JZ7	21421	Test Test	2018-02-28 12:42	u6vknypkdjy3i
TBIUATMT365JZ7	21421	Baseline	2017-12-19 14:28	
TBIUATMT365JZ7	21421	Baseline	2018-02-28 12:59	

Showing 1 to 3 of 3 entries (0 Rows Selected) Export options: CSV | Excel

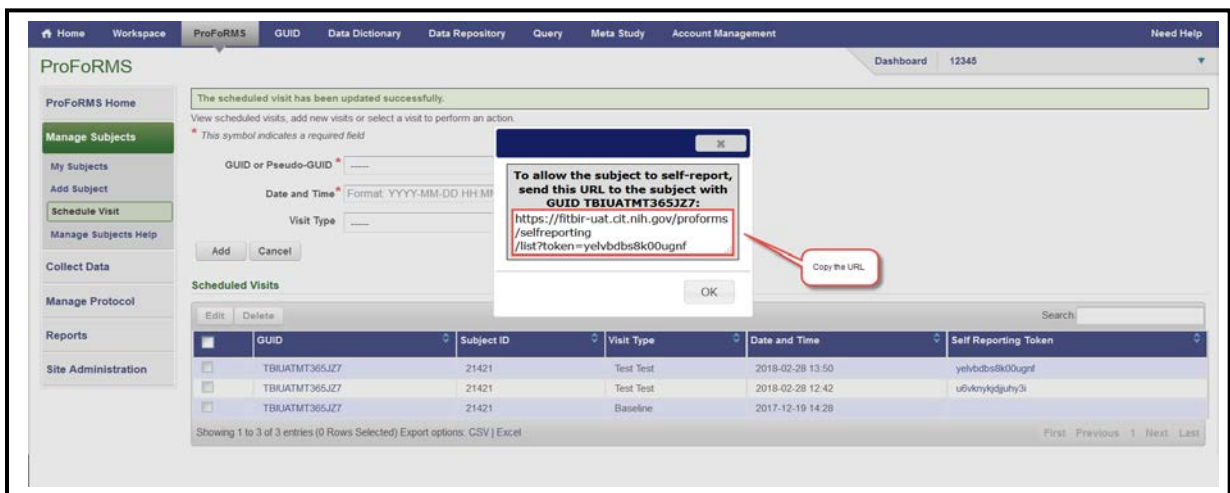
13. The scheduled visit will be updated successfully.



The screenshot shows the ProFoRMS interface with a green message bar at the top stating "The scheduled visit has been updated successfully." Below this, there is a form for adding or updating a visit. The "Scheduled Visits" table is visible, showing three entries for Subject ID 21421. The first two entries are "Test Test" visits, and the third is a "Baseline" visit. The "Self Reporting Token" for the first "Test Test" visit is highlighted with a green circle and an arrow pointing to it.

GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
TBIUATMT365JZ7	21421	Test Test	2018-02-28 13:50	yehvdbbs8k00ugnf
TBIUATMT365JZ7	21421	Test Test	2018-02-28 12:42	u6vkmypgduhy3i
TBIUATMT365JZ7	21421	Baseline	2017-12-19 14:28	

14. To allow the subject to self-report, click on the **Self-Reporting Token** link and send it to the subject with the GUID.



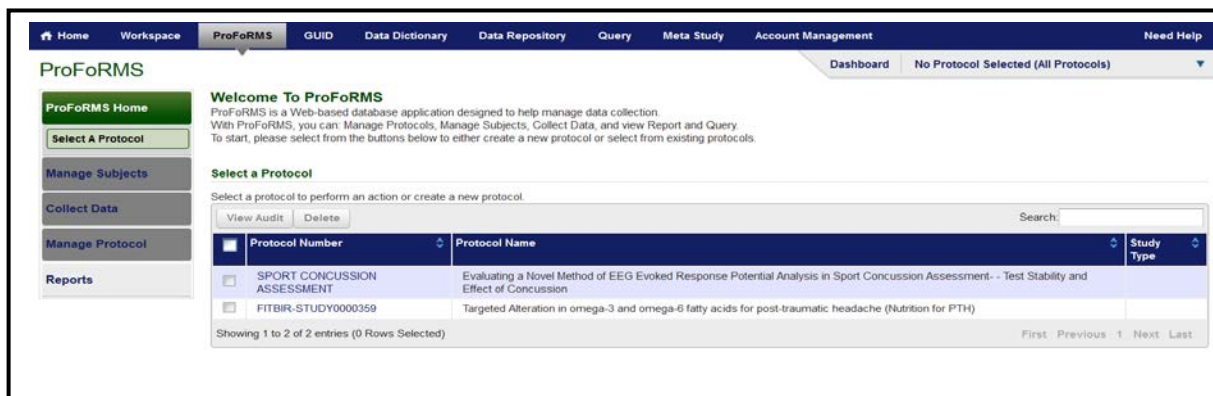
The screenshot shows the ProFoRMS interface with a modal dialog box open. The dialog contains the following text: "To allow the subject to self-report, send this URL to the subject with GUID TBIUATMT365JZ7: https://ftrbtr-uat.ct.nih.gov/proforms/selfreporting/list?token=yehvdbbs8k00ugnf". A red box highlights the URL, and a red arrow points to it with the text "Copy the URL". The background shows the same "Scheduled Visits" table as in the previous screenshot.

3.8.1 E-Binder

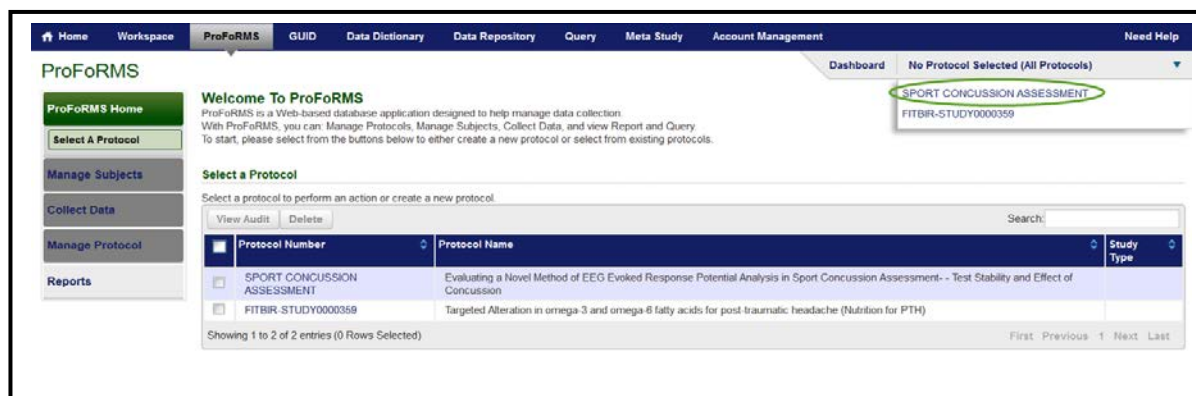
The E-Binder used to Add/Edit documents or view existing documents.

To access this feature: Perform the following actions:

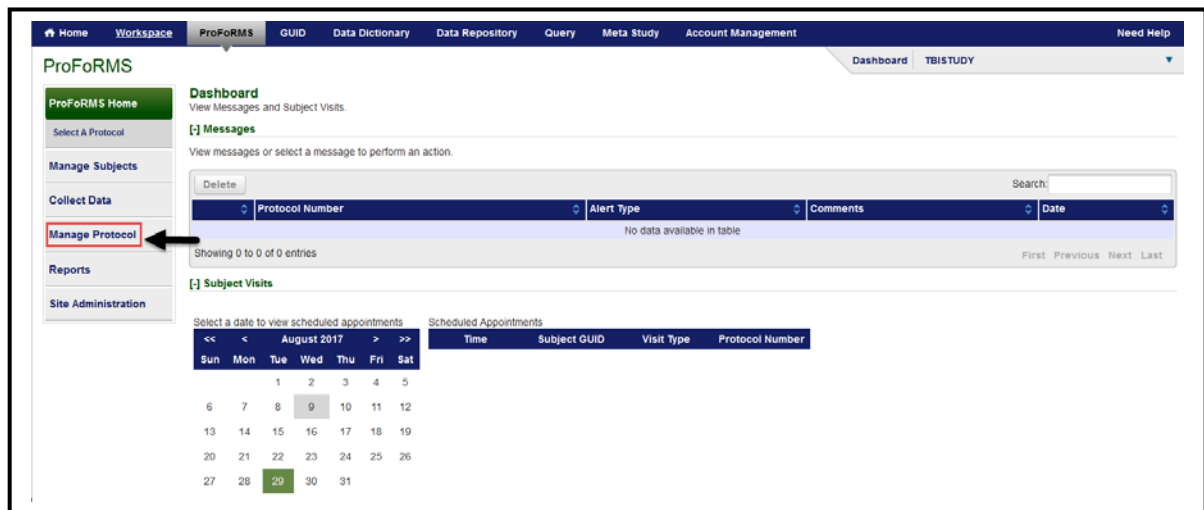
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



4. Click the **E-Binder** button on the left-side tool bar. The E-Binder page appears.



5. Use the **New File** option to upload a new document
6. Use the **New Folder** to create a new folder
7. Use the **Edit** option to edit your uploaded document
8. Use the **Delete** option to delete a document
9. Use the **Download** option to download documents.



3.9 REPORTS

The ProFoRMS reporting feature provides the following report outputs:

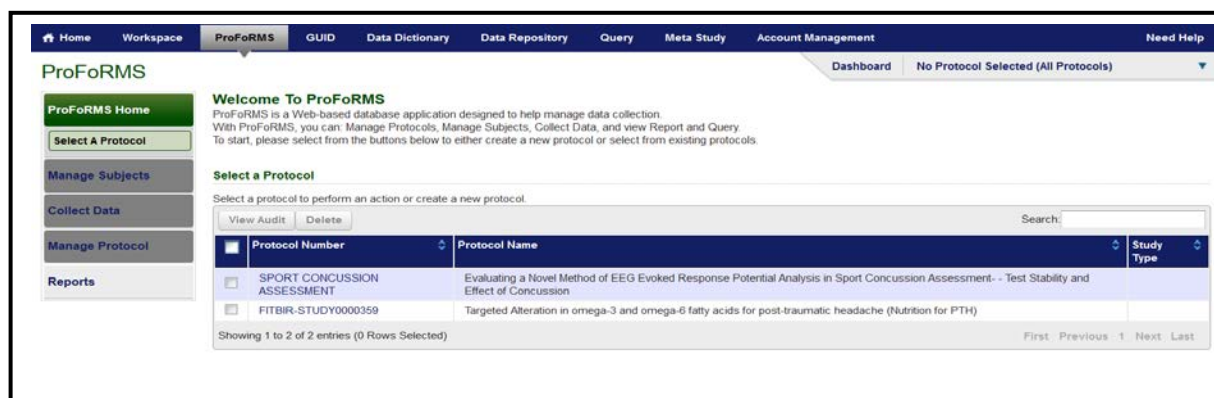
- ❖ Protocol Reports
- ❖ Completed Visits Report
- ❖ Performance Overview
- ❖ GUIDS Without Collections Report
- ❖ Forms Requiring Lock Report
- ❖ Locked Forms Report
- ❖ Form Status by GUID Report
- ❖ Submission Summary
- ❖ Form Status by GUID

3.9.1 Protocol Report

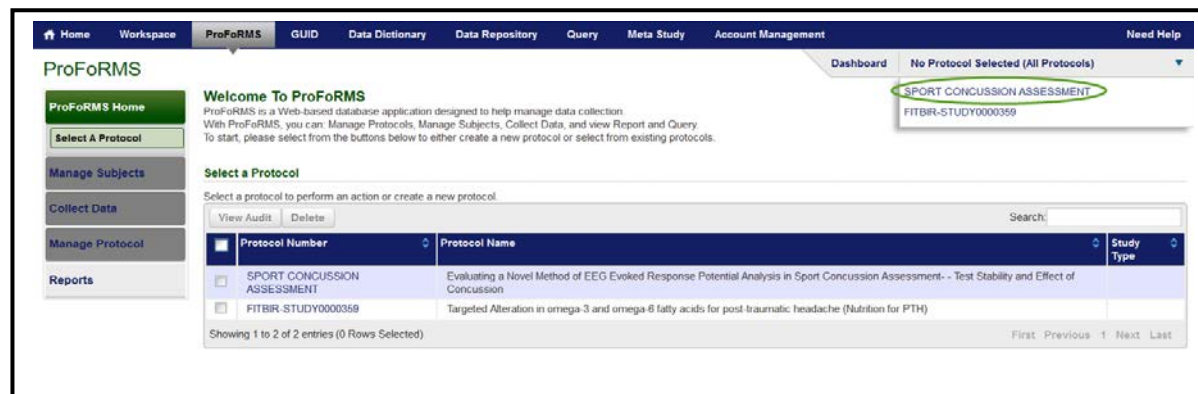
This report will show the protocol by Name, Principal Investigator, Protocol Type, Status, Number of Subjects Enrolled, and Number of Administered Forms of each protocol.

To view Protocol Report: Perform the following actions:

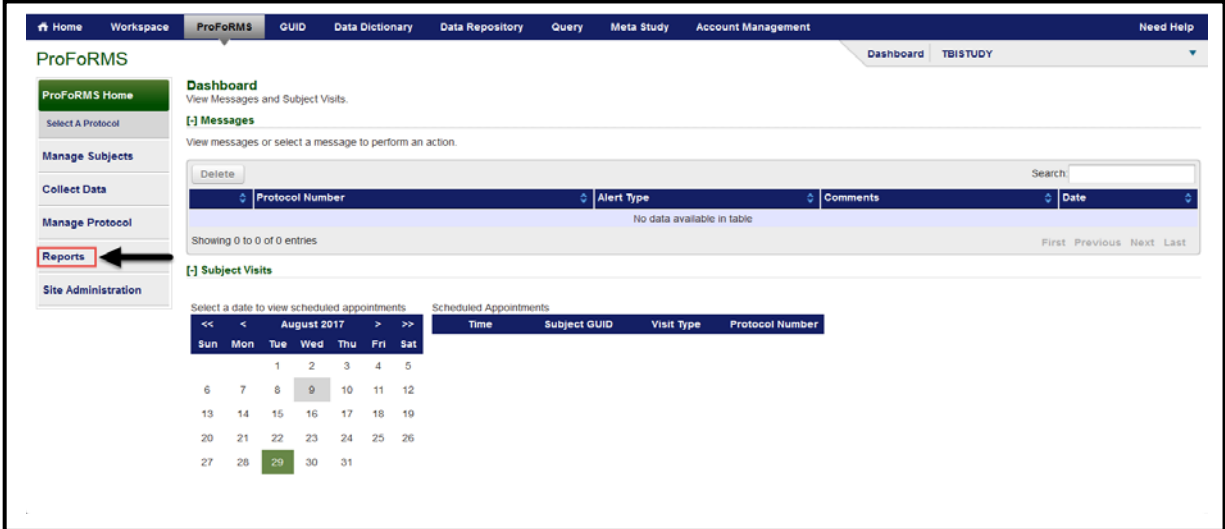
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.

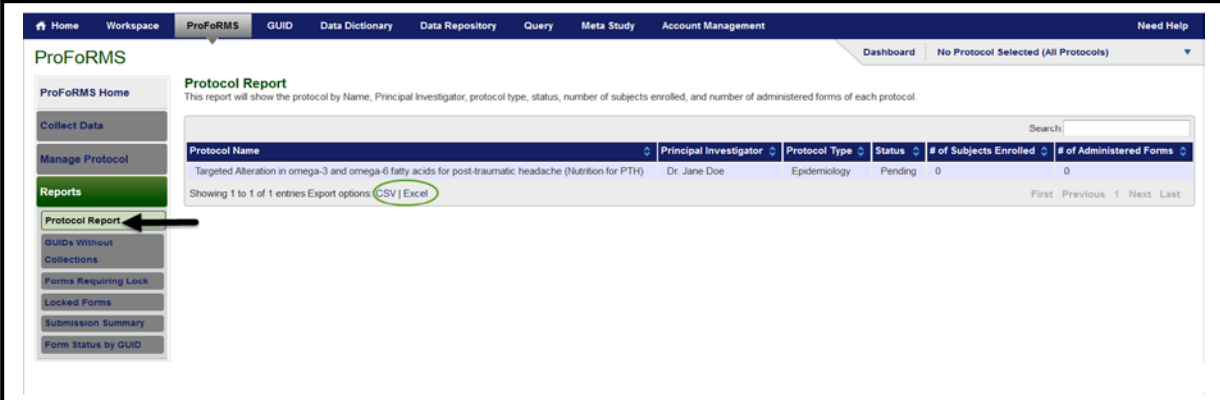


3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



The screenshot shows the ProFoRMS Dashboard. On the left sidebar, the 'Reports' option is highlighted with a red box and an arrow. The main content area displays the 'Dashboard' with sections for 'Messages' and 'Subject Visits'. The 'Messages' section is currently empty, showing 'Showing 0 to 0 of 0 entries'. The 'Subject Visits' section includes a calendar for August 2017, with the 29th highlighted in green.

4. Click the **Protocol Report** on the left-side tool bar. The Protocol Report Information page appears. The report appears showing the Protocol Name, Principal Investigator, Protocol Type, Status, Number of Subjects Enrolled, and Number of Administered forms of each protocol. You may use the export feature to export the report to either CSV or Excel formats.



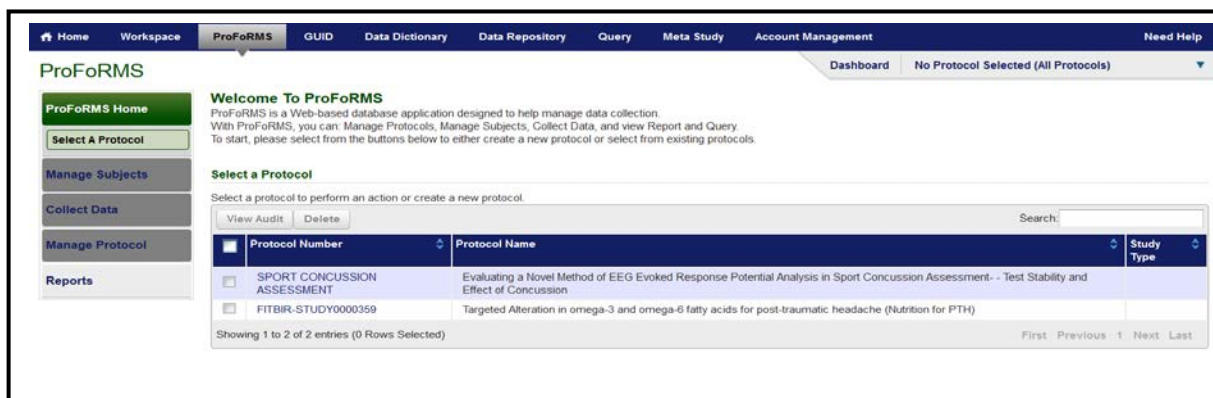
The screenshot shows the ProFoRMS Protocol Report page. On the left sidebar, the 'Protocol Report' option is highlighted with a red box and an arrow. The main content area displays the 'Protocol Report' information. A table lists the protocols, with columns for Protocol Name, Principal Investigator, Protocol Type, Status, # of Subjects Enrolled, and # of Administered Forms. The table contains one entry for 'Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)' by Dr. Jane Doe, with a status of 'Pending' and 0 subjects enrolled and 0 administered forms. The 'Export options' (CSV | Excel) are circled in green.

3.9.2 GUIDS Without Collections Report

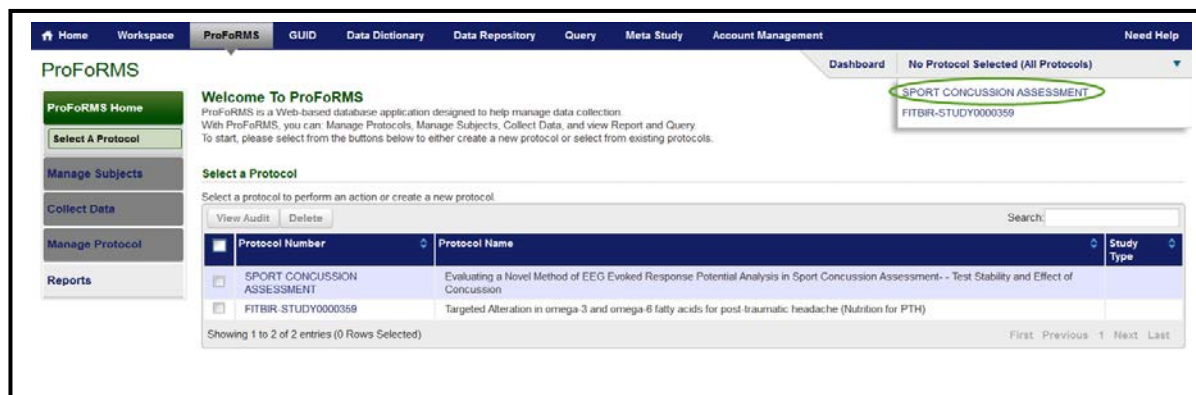
This report lists the GUIDs (including Pseudo-GUIDs) without collections.

To view GUIDS Without Collections Report: Perform the following actions:

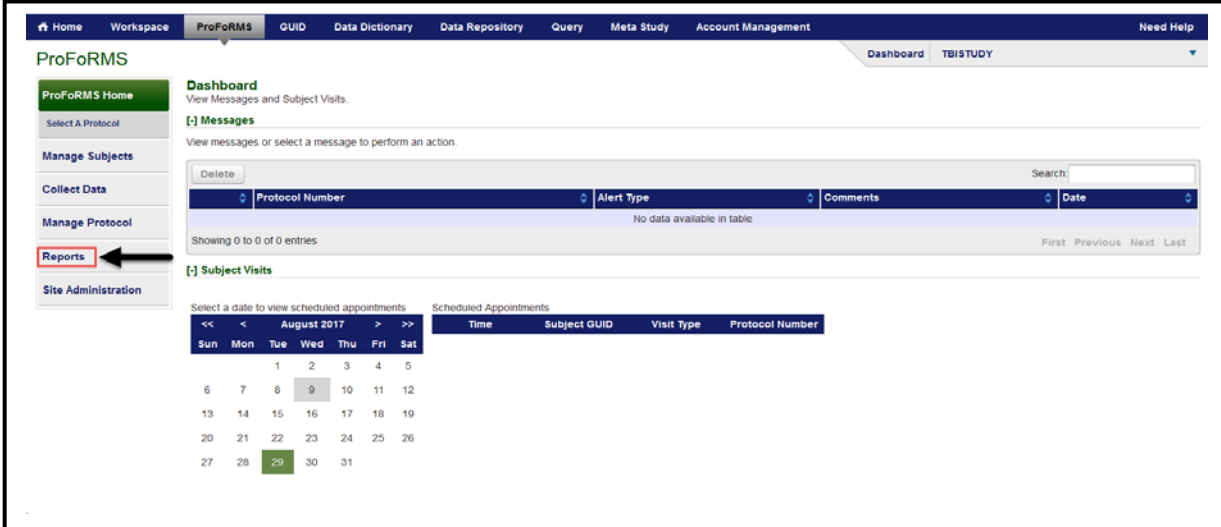
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.

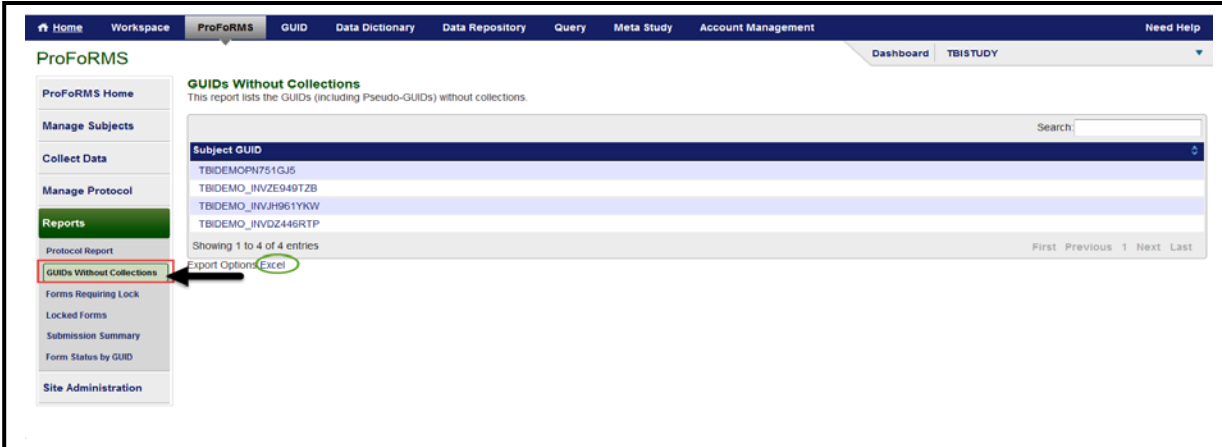


3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



The screenshot shows the ProFoRMS Dashboard. On the left sidebar, the 'Reports' menu item is highlighted with a red box and an arrow. The main content area displays the 'Dashboard' with a 'Messages' section showing a table with columns: Protocol Number, Alert Type, Comments, and Date. Below this is a 'Subject Visits' section with a calendar view for August 2017 and a table of scheduled appointments with columns: Time, Subject GUID, Visit Type, and Protocol Number.

4. Click the **GUIDS Without Collections** on the left-side tool bar. The GUIDS Without Collections Report Information page appears. The report appears showing the Subject GUID. You may use the export feature to export the report to Excel format.



The screenshot shows the 'GUIDS Without Collections' report page. The left sidebar has 'GUIDS Without Collections' highlighted with a red box and an arrow. The main content area displays a table with the following Subject GUIDs: TBIDEMOPN751GJ5, TBIDEMO_INVZE949TZB, TBIDEMO_INVJH961YKW, and TBIDEMO_INVQZ446RTP. Below the table, there is an 'Export Options' button with 'Excel' selected, indicated by a green circle and an arrow.

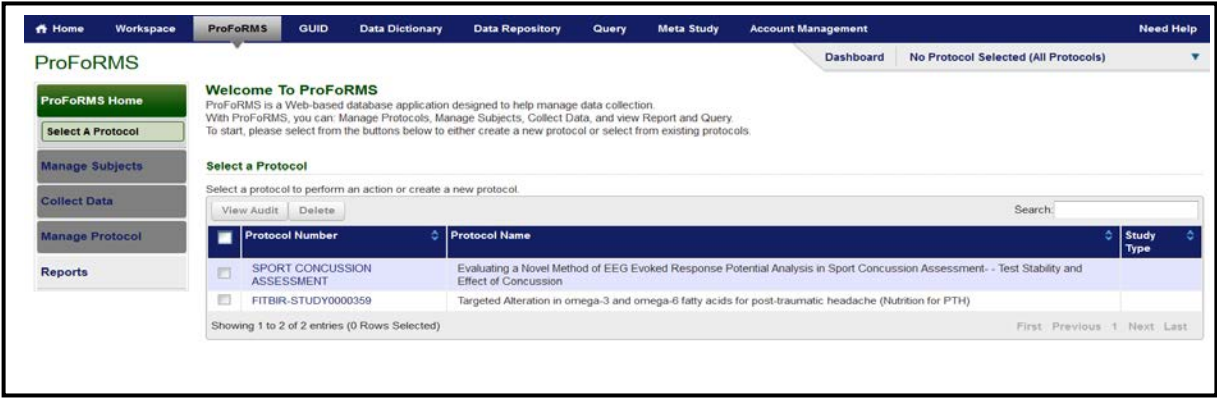
3.9.3 Forms Requiring Lock Report

This report contains the list of collections that are in progress and it has been more than 30 days since creation.

In addition, this table also provides collections that have been completed, but not locked.

To view Forms Requiring Lock Report: Perform the following actions:

1. Navigate to the **ProFoRMS** module



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard No Protocol Selected (All Protocols)

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

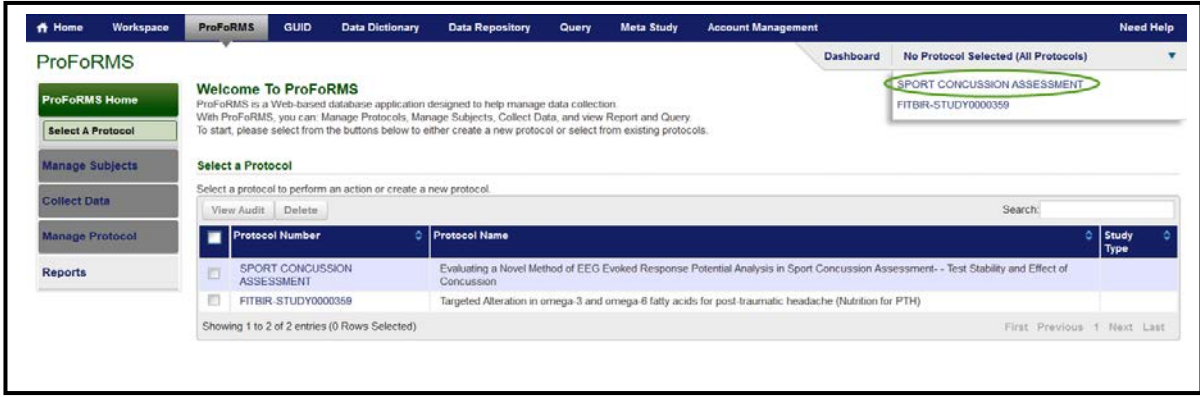
Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Query Meta Study Account Management Need Help

Dashboard No Protocol Selected (All Protocols)

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

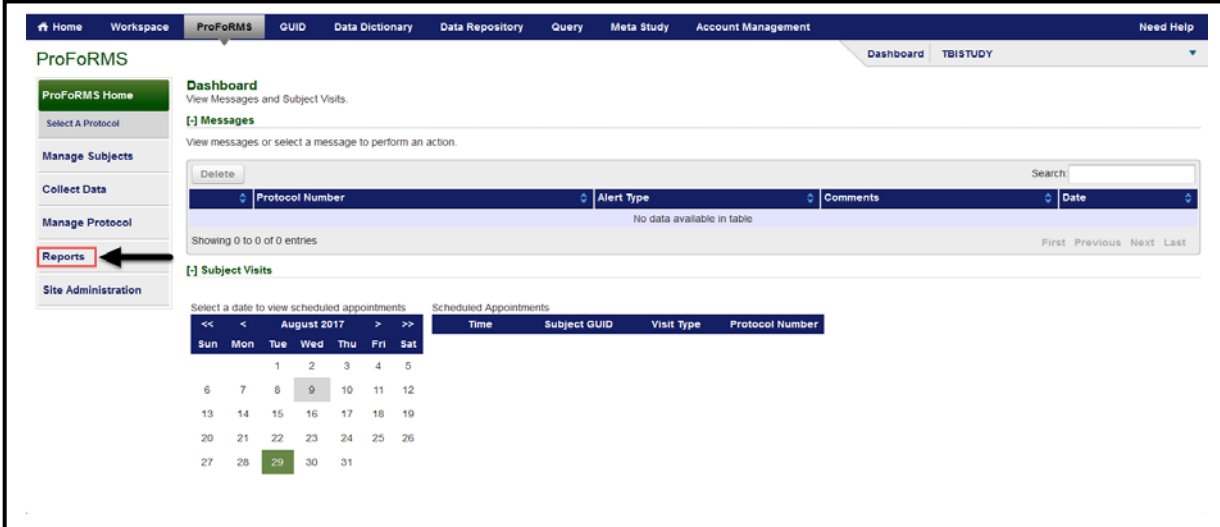
Select a protocol to perform an action or create a new protocol.

View Audit Delete Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion	
FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) First Previous 1 Next Last

3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



ProFoRMS

Dashboard
View Messages and Subject Visits.

[-] Messages
View messages or select a message to perform an action.

Search:

Protocol Number	Alert Type	Comments	Date
No data available in table			

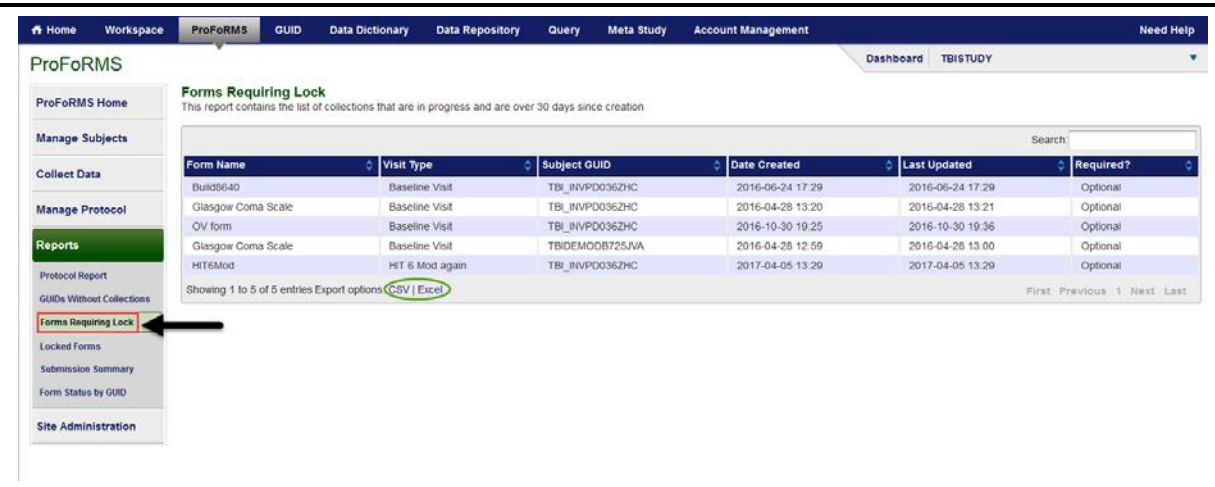
Showing 0 to 0 of 0 entries

[-] Subject Visits
Select a date to view scheduled appointments

Scheduled Appointments

Time	Subject GUID	Visit Type	Protocol Number																																										
<div> <div><<</div> <div><</div> <div>August 2017</div> <div>></div> <div>>></div> </div> <table border="1"> <thead> <tr> <th>Sun</th> <th>Mon</th> <th>Tue</th> <th>Wed</th> <th>Thu</th> <th>Fri</th> <th>Sat</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td>1</td> <td>2</td> <td>3</td> <td>4</td> <td>5</td> </tr> <tr> <td>6</td> <td>7</td> <td>8</td> <td>9</td> <td>10</td> <td>11</td> <td>12</td> </tr> <tr> <td>13</td> <td>14</td> <td>15</td> <td>16</td> <td>17</td> <td>18</td> <td>19</td> </tr> <tr> <td>20</td> <td>21</td> <td>22</td> <td>23</td> <td>24</td> <td>25</td> <td>26</td> </tr> <tr> <td>27</td> <td>28</td> <td>29</td> <td>30</td> <td>31</td> <td></td> <td></td> </tr> </tbody> </table>				Sun	Mon	Tue	Wed	Thu	Fri	Sat			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31		
Sun	Mon	Tue	Wed	Thu	Fri	Sat																																							
		1	2	3	4	5																																							
6	7	8	9	10	11	12																																							
13	14	15	16	17	18	19																																							
20	21	22	23	24	25	26																																							
27	28	29	30	31																																									

4. Click the **Forms Requiring Lock** on the left-side tool bar. The Forms Requiring Lock Report Information page appears. The report appears showing the **Form Name**, **Visit Type**, **Subject GUID ID**, **Date Created**, **Last Updated**, **Required?**. You may use the export feature to export the report to either CSV or Excel format.



ProFoRMS

Forms Requiring Lock
This report contains the list of collections that are in progress and are over 30 days since creation

Search:

Form Name	Visit Type	Subject GUID	Date Created	Last Updated	Required?
Buid9640	Baseline Visit	TBI_INVPO036ZHC	2016-06-24 17:29	2016-06-24 17:29	Optional
Glasgow Coma Scale	Baseline Visit	TBI_INVPO036ZHC	2016-04-28 13:20	2016-04-28 13:21	Optional
QV form	Baseline Visit	TBI_INVPO036ZHC	2016-10-30 19:25	2016-10-30 19:36	Optional
Glasgow Coma Scale	Baseline Visit	TBIDEMOD8725JVA	2016-04-28 12:59	2016-04-28 13:00	Optional
HIT6Mod	HIT 6 Mod again	TBI_INVPO036ZHC	2017-04-05 13:29	2017-04-05 13:29	Optional

Showing 1 to 5 of 5 entries Export options: [CSV](#) | [Excel](#)

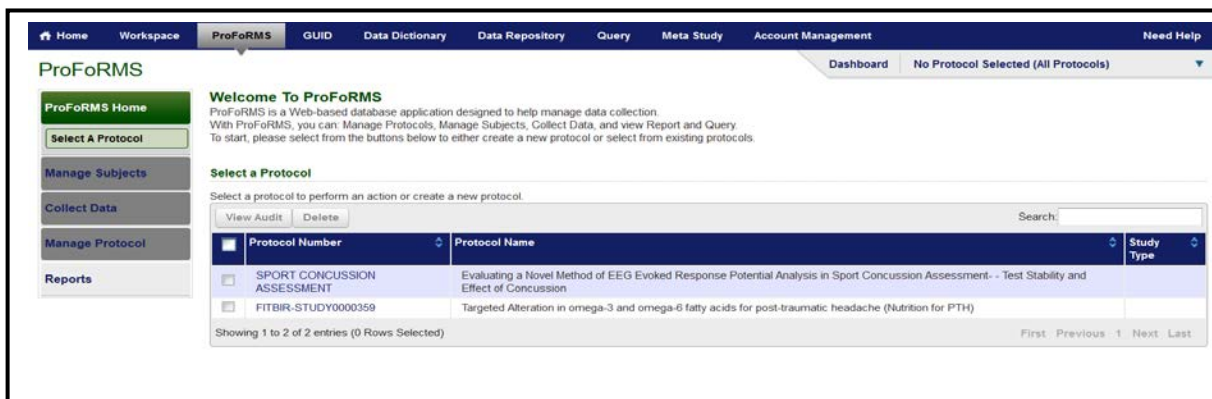
First Previous 1 Next Last

3.9.4 Submission Summary Reports

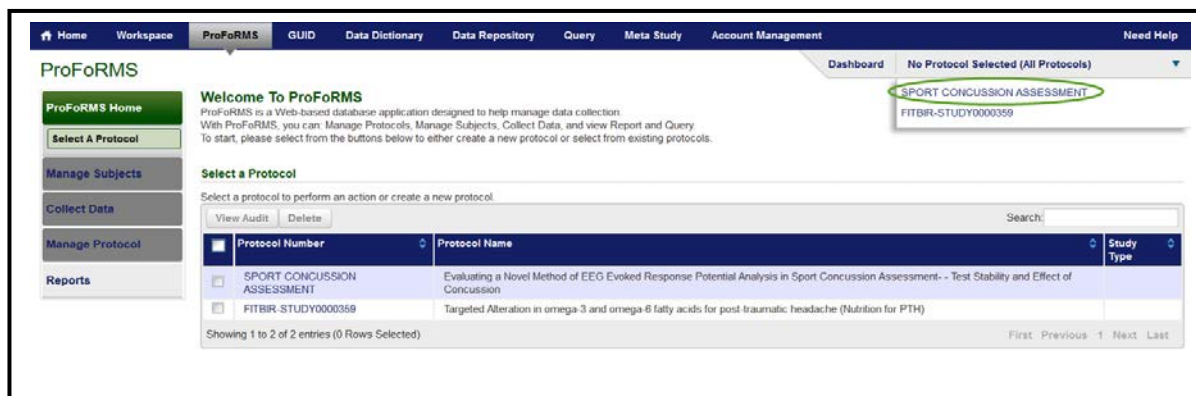
This report lists the status of collections submitted to the data repository for this protocol.

To view Submission Summary Report: Perform the following actions:

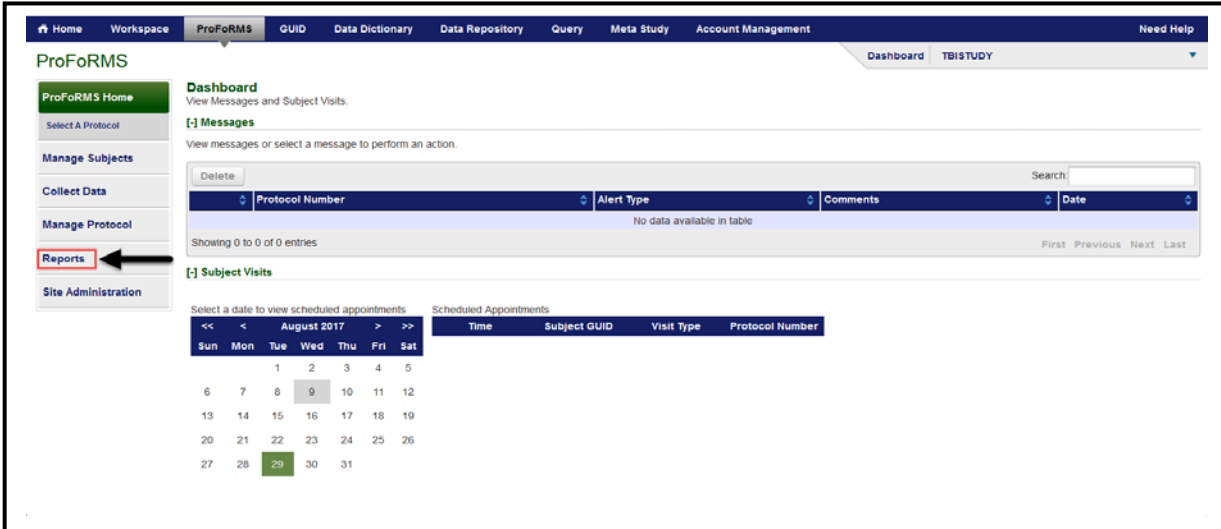
1. Navigate to the **ProFoRMS** module



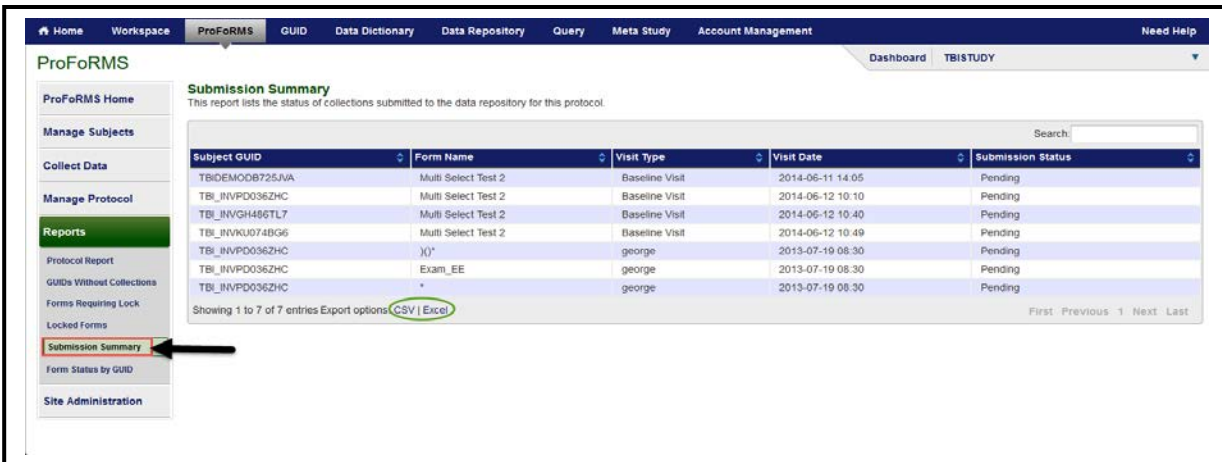
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



- The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



- Click the **Submission Summary Report** on the left-side tool bar. The Submission Summary Report Information page appears. The report appears showing the Subject GUID Form Name, Visit Type, Visit Date, and Submission Status. You may use the export feature to export the report to either CSV or Excel format.

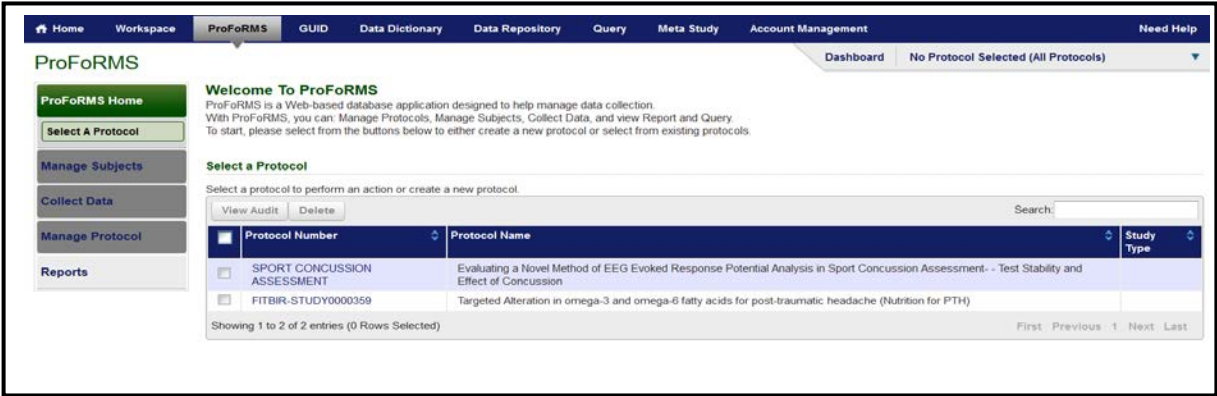


3.9.5 Form Status By GUID Report

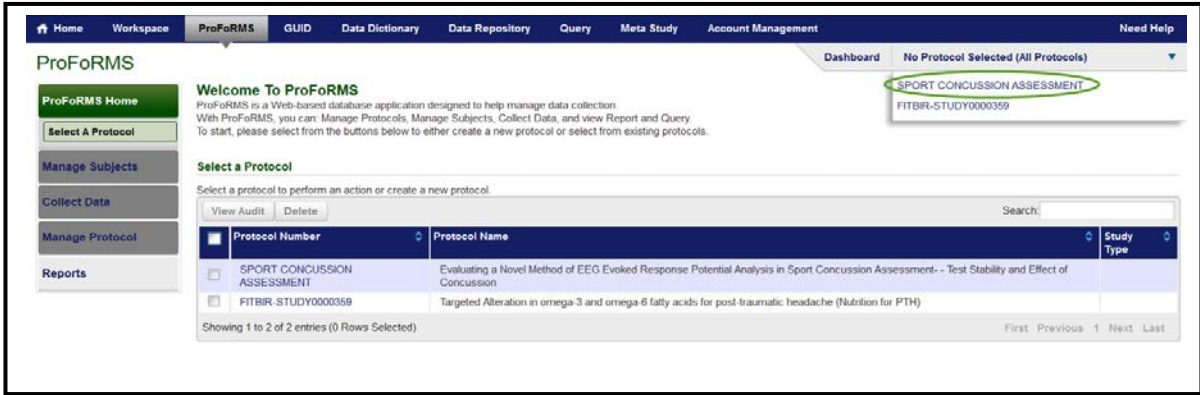
Forms Status by GUID report shows the completion status of forms by GUID for each visit type. To use this report please select a GUID from the drop-down or start typing to auto complete result.

To view Submission Summary Report: Perform the following actions:

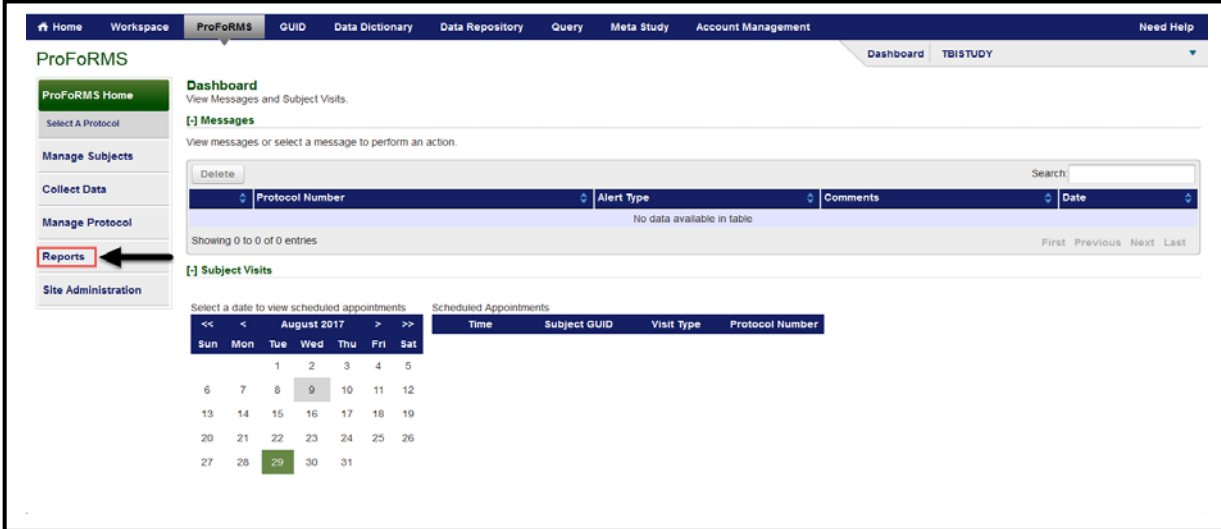
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.

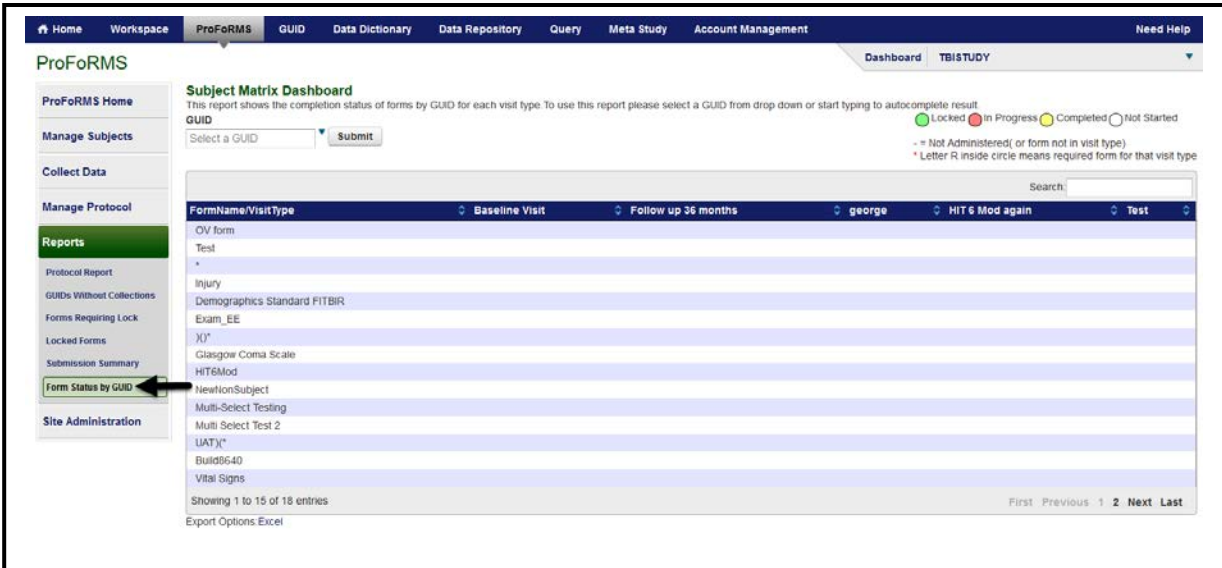


3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



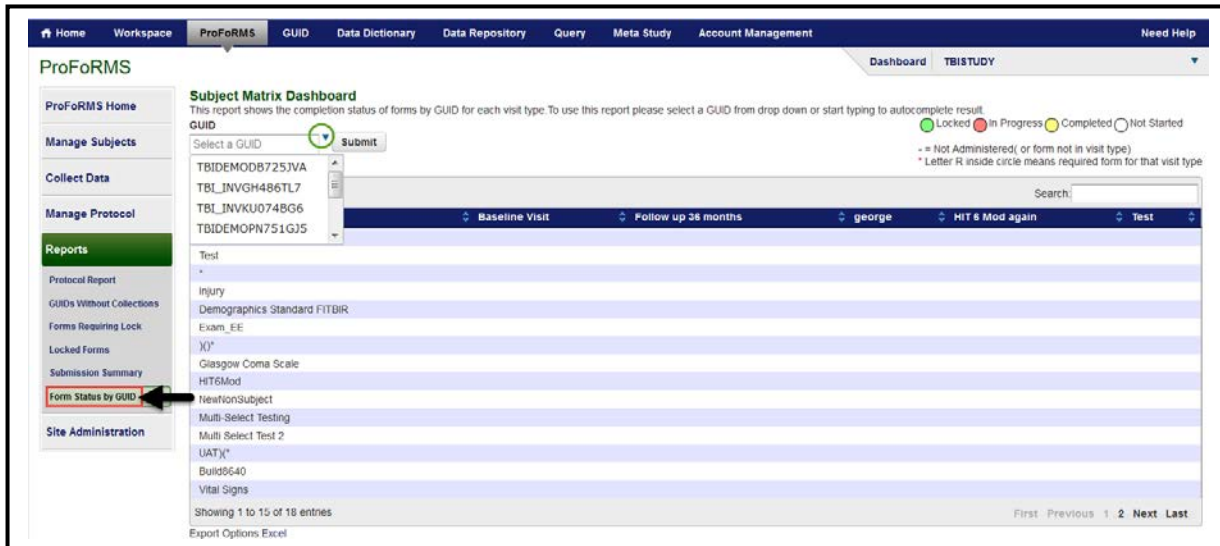
The screenshot shows the ProFoRMS Dashboard. The left sidebar contains a 'Reports' link highlighted with a red box and an arrow. The main content area displays the 'Dashboard' with sections for 'Messages' and 'Subject Visits'. A calendar for August 2017 is visible, showing dates from 1 to 31.

4. Click the **Form Status Submission by GUID** on the left-side tool bar. The report appears listing the competition status of forms by GUID for each visit type. To use this report, you **MUST** select a GUID from the drop-down menu or start typing to autocomplete the result.



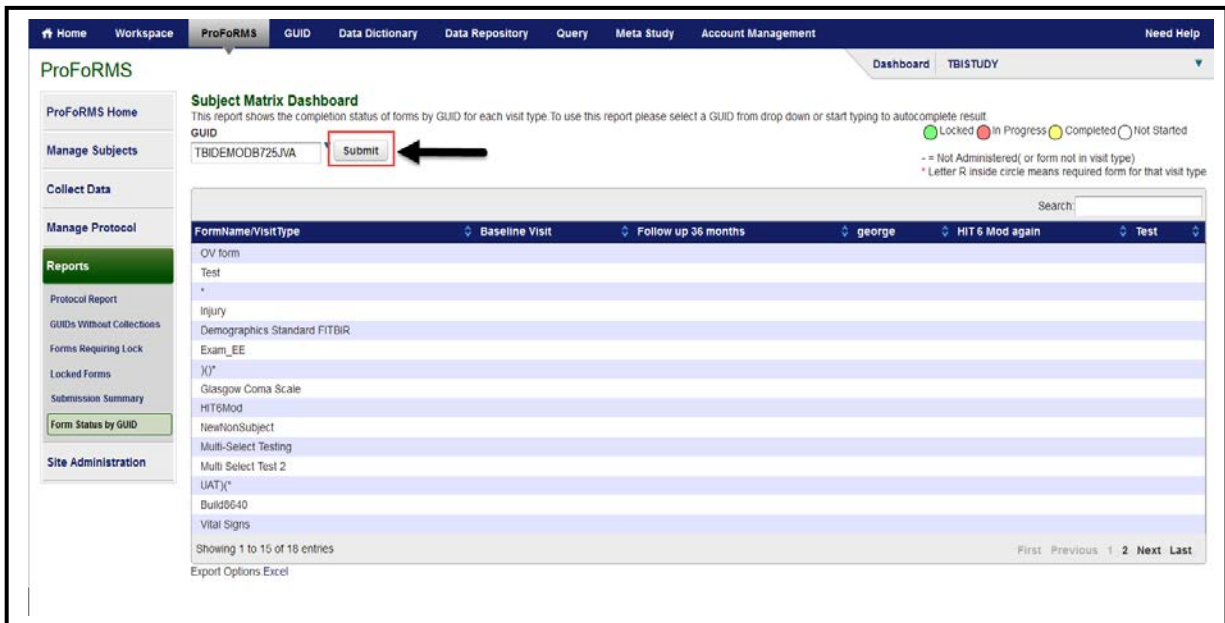
The screenshot shows the 'Form Status Submission by GUID' report. The left sidebar contains a 'Form Status by GUID' link highlighted with a red box and an arrow. The main content area displays a table with columns for 'FormName/VisitType', 'Baseline Visit', 'Follow up 36 months', and 'Test'. A search bar and a 'Submit' button are visible. The table lists various forms and their submission status.

5. Select a GUID from the drop-down menu or start typing to auto-complete the result.



The screenshot shows the ProFoRMS Subject Matrix Dashboard. On the left sidebar, the 'Reports' section is expanded, and 'Form Status by GUID' is selected. In the main content area, the 'GUID' field has a dropdown menu open, displaying a list of GUIDs: TBIDEMOD8725JVA, TBL_INVGH486TL7, TBL_INVKU074BG6, and TBIDEMOPN751GJ5. A red box highlights the 'Submit' button next to the dropdown. The dashboard also displays a table of form completion status for various visit types (Baseline Visit, Follow up 36 months, etc.) and a search bar.

6. Click the **Submit** button.



This screenshot shows the same ProFoRMS Subject Matrix Dashboard, but the GUID dropdown menu is now closed. The GUID field contains the text 'TBIDEMOD8725JVA'. A red box highlights the 'Submit' button, and a black arrow points to it. The dashboard table and search bar are also visible.

7. Click the **Excel** option to export the report.

Home
Workspace
ProFoRMS
GUID
Data Dictionary
Data Repository
Query
Meta Study
Account Management
Need Help

ProFoRMS Home
Manage Subjects
Collect Data
Manage Protocol
Reports
Protocol Report
GUIDs Without Collections
Forms Requiring Lock
Locked Forms
Submission Summary
Form Status by GUID
Site Administration

Subject Matrix Dashboard

This report shows the completion status of forms by GUID for each visit type. To use this report please select a GUID from drop down or start typing to autocomplete result.

GUID
TBIDEMOD8725JVA
Submit

Locked
In Progress
Completed
Not Started

- = Not Administered(or form not in visit type)
* Letter R inside circle means required form for that visit type

FormName/VisitType	Baseline Visit	Follow up 36 months	george	HIT 6 Mod again	Test
OV form		-	-	-	-
Test	-	-	-	-	-
*	-	-		-	-
Injury	-	-	-	-	-
Demographics Standard FITBIR	-	-	-	-	
Exam_EE	-	-		-	-
Y()*	-	-		-	-
Glasgow Coma Scale			-	-	-
HIT6Mod	-	-	-		-
NewNonSubject	-	-	-	-	-
Multi-Select Testing	-	-	-	-	-
Multi Select Test 2		-	-	-	-
UAT()*	-	-		-	-
Build6640		-	-	-	-
Vital Signs	-	-	-	-	-

Showing 1 to 15 of 18 entries
Export Options
Excel

ICON KEY

Notes

Important Information

Things to Note:



Locked
In Progress
Completed
Not Started

- = Not Administered(or form not in visit type)

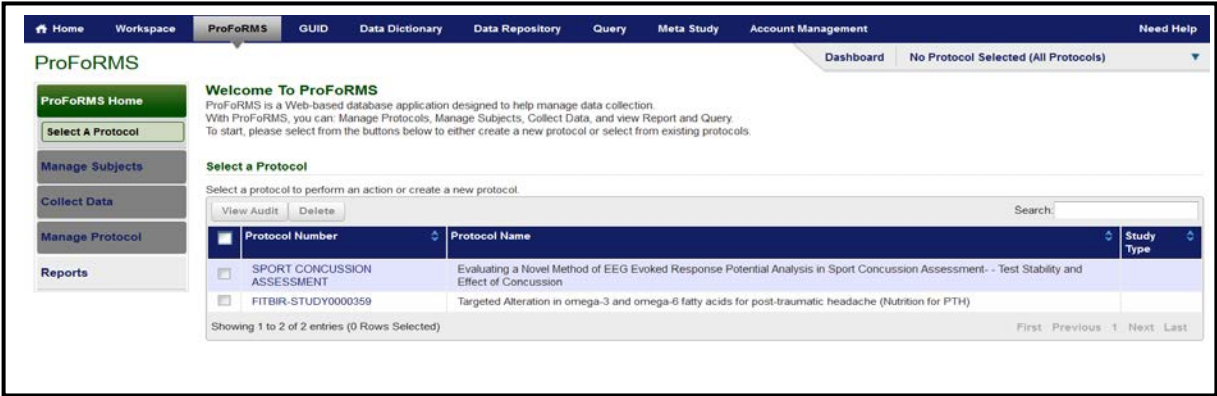
* Letter R inside circle means required form for that visit type

3.9.6 Completed Visits Report

This report shows the total number of subjects within each protocol and the number of subjects that have completed all required forms within each visit type.

To view Completed Visits Report: Perform the following actions:

1. Navigate to the **ProFoRMS** module



ProFoRMS

Dashboard | No Protocol Selected (All Protocols)

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol.

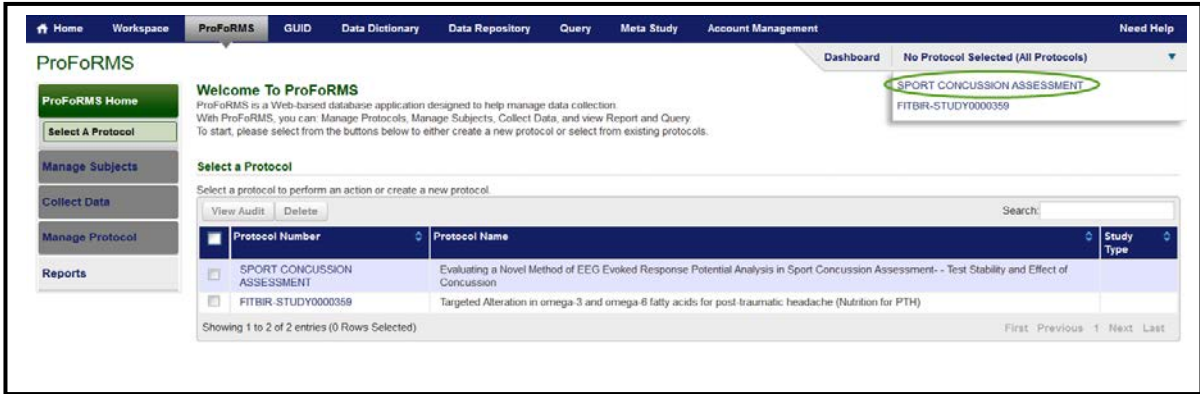
View Audit | Delete

Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment- - Test Stability and Effect of Concussion	
FITBR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

Showing 1 to 2 of 2 entries (0 Rows Selected) | First Previous 1 Next Last

2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



ProFoRMS

Dashboard | No Protocol Selected (All Protocols)

Welcome To ProFoRMS

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol.

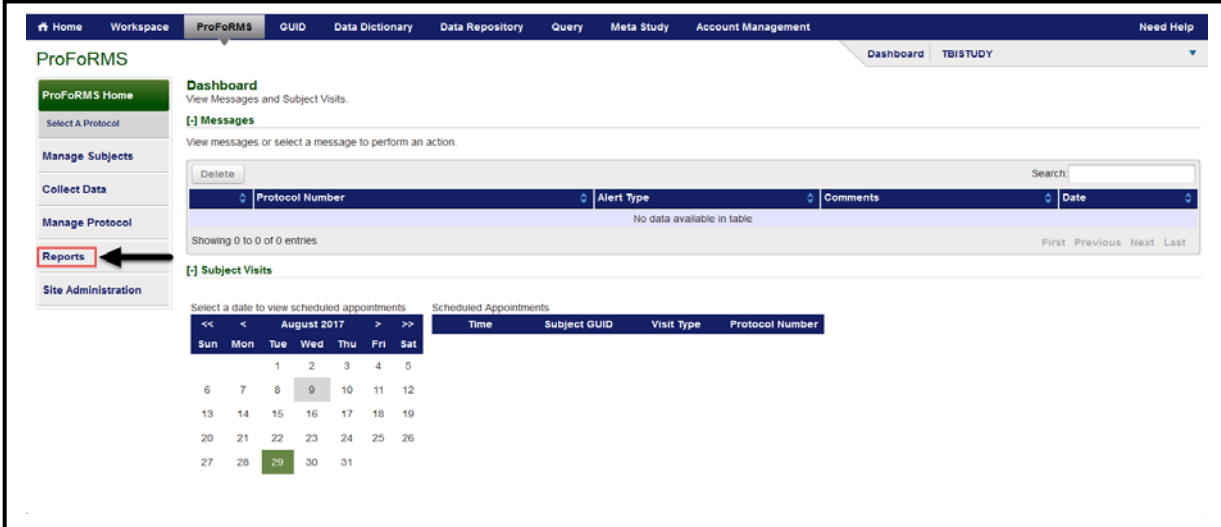
View Audit | Delete

Search:

Protocol Number	Protocol Name	Study Type
SPORT CONCUSSION ASSESSMENT	Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment- - Test Stability and Effect of Concussion	
FITBR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	

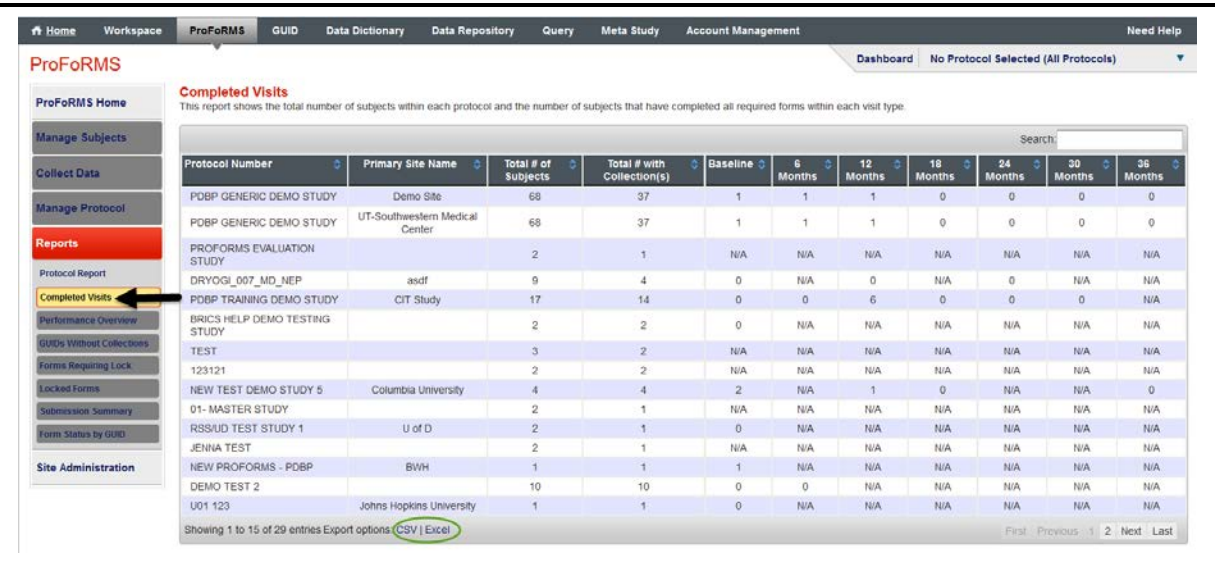
Showing 1 to 2 of 2 entries (0 Rows Selected) | First Previous 1 Next Last

3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



The screenshot shows the ProFoRMS Dashboard. On the left sidebar, the 'Reports' menu item is highlighted with a red box and an arrow. The main content area displays the 'Dashboard' with sections for 'Messages' and 'Subject Visits'. A calendar for August 2017 is visible, showing dates from 1 to 31.

4. Click the **Completed Visits** on the left-side tool bar. The report appears listing the Protocol Number, Primary Site Name, Total Number of Subjects, Total Number with Collections, Baselines, 6 Month, 12 Months, 18 Months, 24 Months, 36 Months, 42 Months, 48 Months, 54 Months, 60 Months, 72 Months. **Note:** This report is only available to the PDBP. You may use the export feature to export the report to either CSV or Excel format. N/A signifies that no data has been collected for that visit type.



The screenshot shows the 'Completed Visits' report in ProFoRMS. The left sidebar has 'Completed Visits' highlighted with a red box and an arrow. The main content area displays a table with the following columns: Protocol Number, Primary Site Name, Total # of Subjects, Total # with Collection(s), Baseline, 6 Months, 12 Months, 18 Months, 24 Months, 30 Months, and 36 Months. The table lists 29 entries. At the bottom, there is a note: 'Showing 1 to 15 of 29 entries Export options CSV | Excel'.

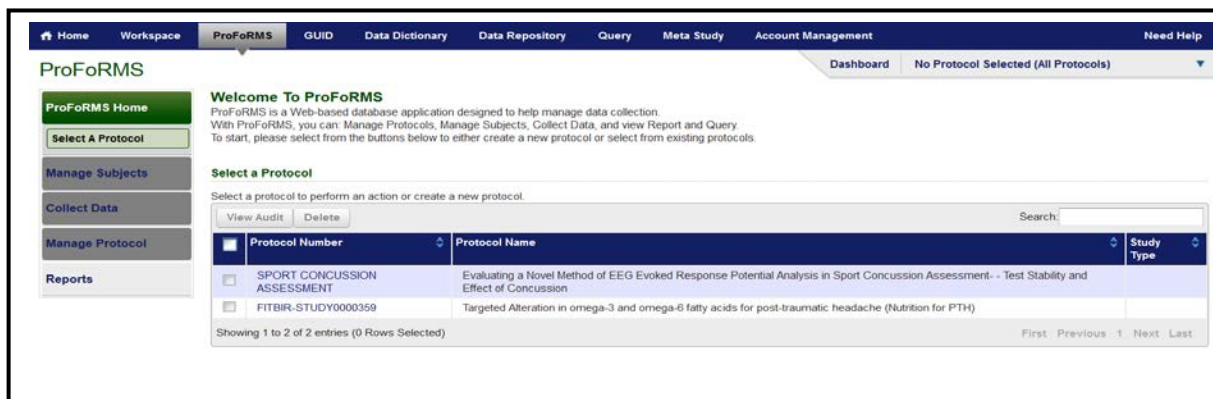
Protocol Number	Primary Site Name	Total # of Subjects	Total # with Collection(s)	Baseline	6 Months	12 Months	18 Months	24 Months	30 Months	36 Months
PDBP GENERIC DEMO STUDY	Demo Site	68	37	1	1	1	0	0	0	0
PDBP GENERIC DEMO STUDY	UT-Southwestern Medical Center	68	37	1	1	1	0	0	0	0
PROFORMS EVALUATION STUDY		2	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
DRYOGI_007_MD_NEP	asdf	9	4	0	N/A	0	N/A	0	N/A	N/A
PDBP TRAINING DEMO STUDY	CIT Study	17	14	0	0	6	0	0	0	N/A
BRICS HELP DEMO TESTING STUDY		2	2	0	N/A	N/A	N/A	N/A	N/A	N/A
TEST		3	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
123121		2	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NEW TEST DEMO STUDY 5	Columbia University	4	4	2	N/A	1	0	N/A	N/A	0
01- MASTER STUDY		2	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RSSUD TEST STUDY 1	U of D	2	1	0	N/A	N/A	N/A	N/A	N/A	N/A
JENNA TEST		2	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NEW PROFORMS - PDBP	BWH	1	1	1	N/A	N/A	N/A	N/A	N/A	N/A
DEMO TEST 2		10	10	0	0	N/A	N/A	N/A	N/A	N/A
U01 123	Johns Hopkins University	1	1	0	N/A	N/A	N/A	N/A	N/A	N/A

3.9.7 Performance Overview Report

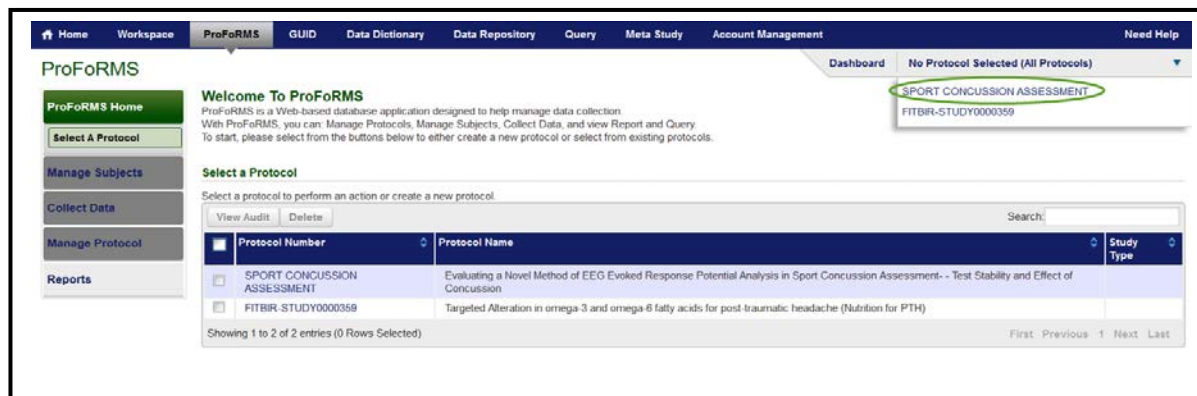
This report shows the total number of In Progress and Locked forms.

To view Performance Overview Report: Perform the following actions:

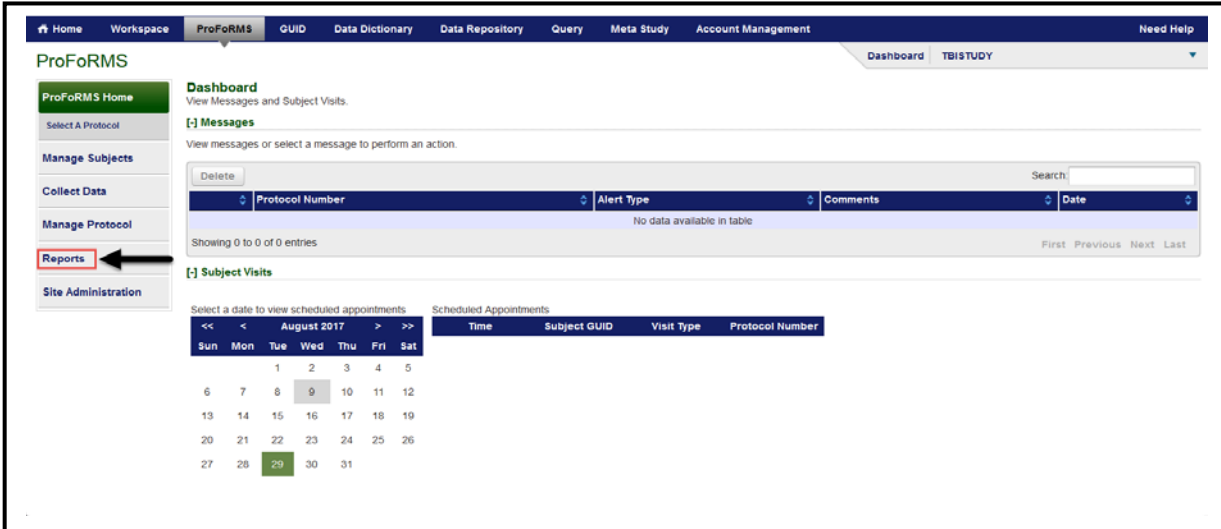
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.

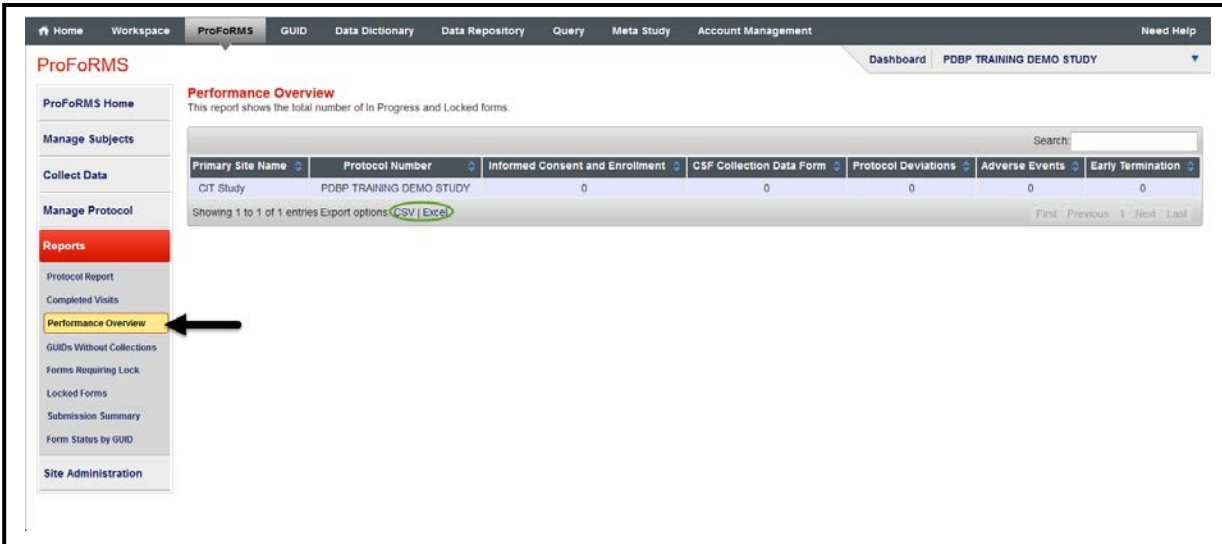


3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



The screenshot shows the ProFoRMS interface. On the left, a vertical menu contains options: Home, Workspace, ProFoRMS, GUID, Data Dictionary, Data Repository, Query, Meta Study, Account Management, and Need Help. Below these are ProFoRMS Home, Select A Protocol, Manage Subjects, Collect Data, Manage Protocol, **Reports** (highlighted with a red box and an arrow), and Site Administration. The main area displays the 'Dashboard' for 'TBISTUDY'. It includes a 'Messages' section with a table (empty) and a 'Subject Visits' section with a calendar for August 2017 and a table of scheduled appointments.

4. Click the **Performance Overview** on the left-side tool bar. The report appears listing the Primary Site Name, Protocol Number, Informed Consent and Enrollment, CSF Collectons, Protocol Deviations, Adverse Events, Early Termination, **Note: This report is only available to the PDBP.** You may use the export feature to export the report to either CSV or Excel format.



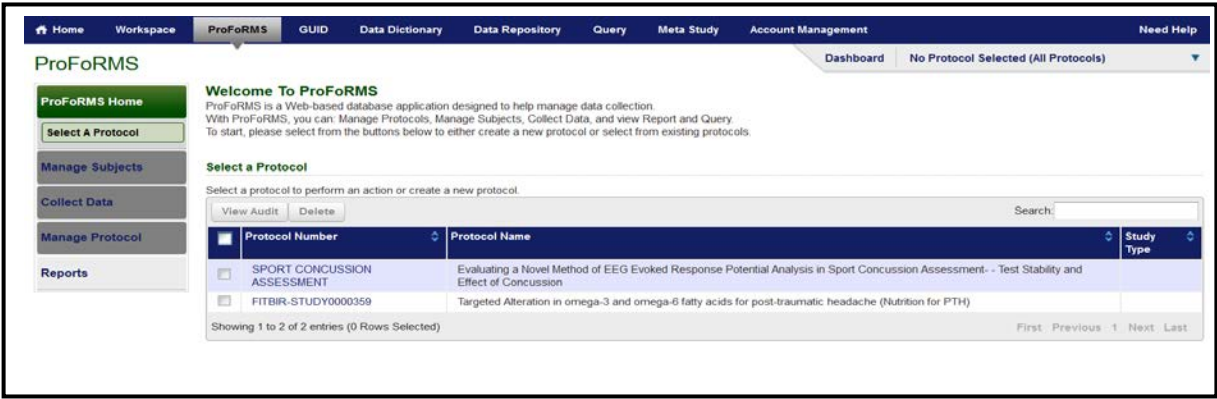
The screenshot shows the ProFoRMS 'Performance Overview' report. The left sidebar menu is expanded, showing options like Protocol Report, Completed Visits, GUIDs Without Collections, Forms Requiring Lock, Locked Forms, Submission Summary, Form Status by GUID, and Site Administration. The 'Performance Overview' option is highlighted with a yellow box and an arrow. The main area displays the report for 'PDBP TRAINING DEMO STUDY'. It includes a table with columns: Primary Site Name, Protocol Number, Informed Consent and Enrollment, CSF Collection Data Form, Protocol Deviations, Adverse Events, and Early Termination. The table shows one entry for 'CIT Study' with zero values in the other columns. Below the table, there are export options for CSV and Excel, with 'CSV' and 'Excel' circled in green.

3.9.8 Locked Forms Report

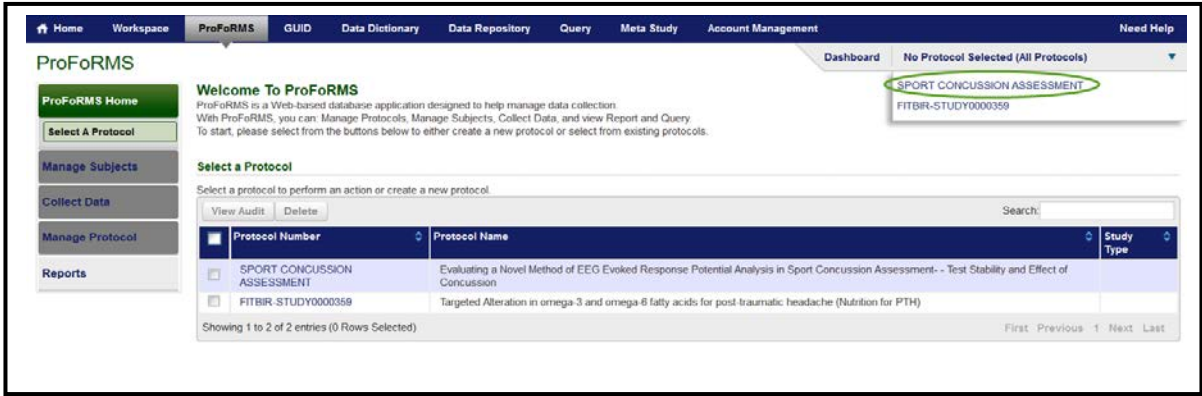
This report shows the forms that are completed in data collection, and it is filled out by subject.

To view Performance Overview Report: Perform the following actions:

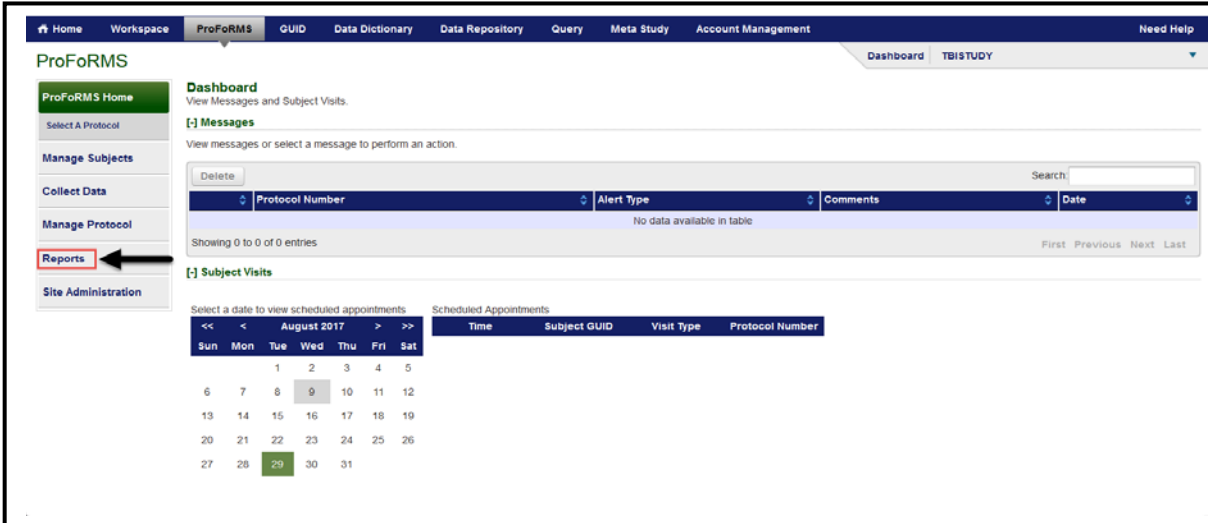
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.

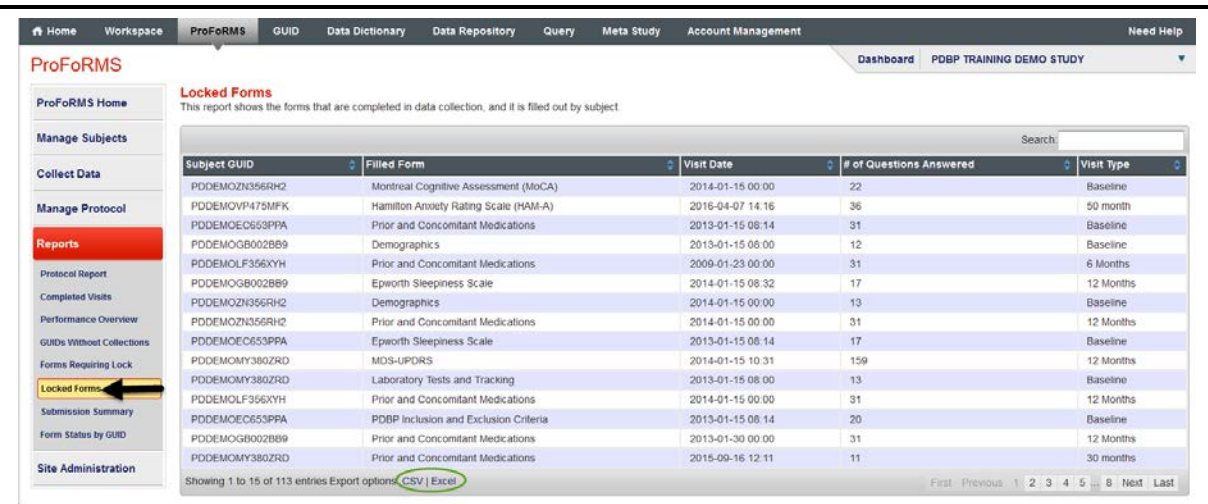


3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



The screenshot shows the ProFoRMS Dashboard interface. On the left sidebar, the 'Reports' option is highlighted with a red box and an arrow. The main content area displays the 'Dashboard' for the 'TBISTUDY' protocol. It includes sections for 'Messages' (view messages or select a message to perform an action) and 'Subject Visits' (select a date to view scheduled appointments). A calendar for August 2017 is shown, with the 9th highlighted. The 'Subject Visits' table has columns for Time, Subject GUID, Visit Type, and Protocol Number.

4. Click the **Locked Forms** on the left-side tool bar. The report appears listing the Subject GUID, Filled Form, Visit Date, Number of Questions Answered and Visit Type. **Note:** This report is only available to the PDBP. You may use the export feature to export the report to either CSV or Excel format.



The screenshot shows the 'Locked Forms' report in ProFoRMS. The left sidebar has 'Locked Forms' highlighted with a red box and an arrow. The main content area displays a table of locked forms. The table has columns for Subject GUID, Filled Form, Visit Date, # of Questions Answered, and Visit Type. The table lists various forms, including Montreal Cognitive Assessment (MoCA), Hamilton Anxiety Rating Scale (HAM-A), Prior and Concomitant Medications, Demographics, Epworth Sleepiness Scale, and MOS-UPDRS. At the bottom, there is a note: 'Showing 1 to 15 of 113 entries Export options: CSV | Excel'.